

STERILIZATION ASSEMBLY DEVELOPMENT LABORATORY
"MONITORING PLAN"

15 August 1967

Task 6.0

JPL CONTRACT 951624

THIS WORK WAS PERFORMED FOR THE JET PROPULSION
LABORATORY, CALIFORNIA INSTITUTE OF TECHNOLOGY,
SPONSORED BY THE NATIONAL AERONAUTICS AND SPACE
ADMINISTRATION UNDER CONTRACT NAS7-100.

Prepared by

AVCO CORPORATION
SPACE SYSTEMS DIVISION
Lowell, Massachusetts

GPO PRICE \$ _____

CFSTI PRICE(S) \$ _____

Hard copy (HC) 300

Microfiche (MF) 65

for

ff 653 July 65

JET PROPULSION LABORATORY
CALIFORNIA INSTITUTE OF TECHNOLOGY
PASADENA, CALIFORNIA



FACILITY FORM 602

N68-22519

(ACCESSION NUMBER)

(THRU)

180

(PAGES)

(CODE)

CR #94341

(NASA CR OR TMX OR AD NUMBER)

05

(CATEGORY)

-NOTE-

This report contains information prepared by AVCO Corporation, Space Systems Division, under JPL subcontract. Its content is not necessarily endorsed by the Jet Propulsion Laboratory, California Institute of Technology, or the National Aeronautics and Space Administration

STERILIZATION ASSEMBLY DEVELOPMENT LABORATORY

"MONITORING PLAN"

15 August 1967

Task 6.0

JPL CONTRACT 951624

PREPARED BY: J. B. Mathews
J. B. Mathews, Facilities
AVCO CORPORATION

APPROVED BY: A. Robins
A. Robins, Facilities Manager
AVCO CORPORATION

APPROVED BY: E. J. Lunn
E. J. Lunn, CSO Manager
AVCO CORPORATION

APPROVED BY: T. Gavin By J.F.
T. Gavin, Quality Assurance
JET PROPULSION LAB

APPROVED BY: W. Paik
W. Paik, Sterilization
JET PROPULSION LABORATORY

APPROVED BY: G. H. Redmann
G. H. Redmann, SADL Project Mgr.
JET PROPULSION LABORATORY

JET PROPULSION LABORATORY

CALIFORNIA INSTITUTE OF TECHNOLOGY

PASADENA, CALIFORNIA

CHANGES

Page No.	Description	Date
AVSSD-0317-67-CR	Initial Issue	15 August 1967

TABLE OF CONTENTS

PRECEDING PAGE BLANK NOT FILMED.

	<u>Page</u>
A. SCOPE	1
B. APPLICABLE DOCUMENTS	2
C. EQUIPMENT REQUIRED	3
D. QUALITY ASSURANCE PROVISIONS	4
E. SADL MONITORING PLAN	6
I. FACILITY ENVIRONMENTAL & SUPPORT SYSTEMS	6
1.1 System AC-1 (Assembly Room #140)	6
1.2 System AC-2 (Air Lock & Sterile Transfer Room #139/141)	10
1.3 System AC-3 (Dressing Room #138)	14
1.4 System AC-4 (Bio-Lab Room #127/144)	18
1.5 Monitoring of EASL Systems	19
1.6 Other Support Systems	34
1.7 Personnel Monitoring Control	35
1.8 HEPA Filters	36
II. LAB EQUIPMENT	38
2.1 ETO Decontamination Chamber	38
2.2 Terminal Sterilization Chamber	39
2.3 Multiple Sensing Stations (SADL)	40
2.4 Oxygen Sensing Stations	40
2.5 Single Door Steam Sterilizer (D-1)	41
2.6 ETO Decontamination Chamber (D-2) and (D-5)	41
2.7 Two-Door Steam Sterilizer (D-3) and (D-4)	41
2.8 Two-Ton Electric Hoist (Item 11)	42
2.9 Two-Door Dry Heat Sterilizer (D-8)	42

TABLE OF CONTENTS (cont'd)

	<u>Page</u>
2.10 Glass Dryer (Item 9)	42
2.11 High Speed Refrigerated Centrifuge (Item 6)	43
2.12 Incubator, Humidity Controlled (Item 4)	43
2.13 Laminar Flow Bench (Baker Edgegard Hood) (Item 2)	43
2.14 Laboratory Glassware Washer (Item 8)	44
2.15 Refrigerator (Item 5)	44
2.16 Fume Hood (Item 3)	45
2.17 Laminar Flow Benches (Pure-Air Horizontal Flow) (Item 1)	45
 TEST REQUIREMENTS AND DETAILED TEST PROCEDURES (combined)	 APPENDIX A
 DATA SHEETS FOR TEST PROCEDURES	 APPENDIX B

FIGURES

	<u>Page</u>
1. General Layout of SADL	5
2. Location of Monitoring Sites in EASL Facility	27
3. Location of Sampling Sites in EASL Facility	28
4. EASL Bio-Assay Room Particulate Count Test Points	29
5. EASL Bio-Assay Room Temperature and Humidity Test Points	30
6. EASL Bio-Assay Room Air Velocity Test Points	31
7. EASL Dressing Room Air Velocity and Particulate Count Test Points ..	32
8. EASL Dressing Room Temperature and Humidity Test Points	33
9. SADL Dressing Room Temperature Test Points	B-33
10. SADL Dressing Room Air Velocity Test Points	B-34
11. SADL Dressing Room Particulate Count Test Points	B-35
12. SADL Dressing Room Relative Humidity Test Points	B-36
13. SADL Airlock Temperature and Relative Humidity Test Points	B-40
14. SADL Airlock Particulate Count Test Points	B-41
15. SADL Assembly Room Temperature and Relative Humidity Test Points ...	B-47
16. SADL Assembly Room Air Velocity Test Points	B-48
17. SADL Assembly Room Particulate Count Test Points	B-49
18. SADL Sterile Transfer Temperature and Relative Humidity Test Points.	B-53
19. SADL Sterile Transfer Particulate Count Test Points	B-54
20. SADL Dressing Room Filter Bank Monitoring Grid	B-56
21. SADL Assembly Room Filter Bank Monitoring Grid	B-59
22. EASL Dressing Room Filter Bank Monitoring Grid	B-61
23. EASL Bio-Assay Room Filter Bank Monitoring Grid	B-64

ABBREVIATIONS

SADL	Sterilization Assembly Development Laboratory
EASL	Experimental Assembly and Sterilization Laboratory
ETO	A Gas Mixture of 12% Ethylene Oxide and 88% Freon - 12
MDL	Model
Ft	Feet
W.G.	Water Gauge
°F.	Degrees Fahrenheit
°C.	Degrees Centigrade
%	Percent
Bio-lab	Biology Laboratory
TSC	Terminal Sterilization Chamber
P.S.I.	Pounds Per Square Inch
Adj.	Adjustment
V.	Volt
In.	Inch
FPM	Feet Per Minute
Equiv.	Equivalent
Max.	Maximum
Min.	Minimum
DOP	Diocetyl Pthalate
HEPA	High Efficiency Particulate Air

A. SCOPE.

The SADL Monitoring Plan consists of the test requirements and test procedures to be used to demonstrate: (1) that the SADL and EASL Laminar Flow rooms meet the requirements of a Class 100 cleanroom as defined by Federal Standard No. 209a^{*} and (2) that the facility lab equipment permanently installed in the facility is operating as required for acceptable facility activities.

This monitoring plan is limited to the mechanical acceptance criteria. Biological monitoring requirements will be included after the facility has been operated to determine requirements.

Figure 1 presents the SADL first floor plan with room identifications and equipment locations.

* Or as modified by the basic design specification of EASL or SADL.

B. APPLICABLE DOCUMENTS.

1. Sterilization Assembly Development Laboratory Certification Plan, Reorder No. 67-104.
2. Federal Standard No. 209A, dated 10 August 1966.
3. Sandia Corporation Report SG 17859, "Leak Testing of HEPA Filter Installation in Laminar Flow Clean Rooms".
4. JPL Specification 7094, ETO Decontamination Chamber SADL - Bldg 233, September 1966.
5. JPL Specification ES 501433, Detail Requirements for Terminal Sterilization Chamber, 6 December 1966 (as amended).

C. EQUIPMENT REQUIRED.

1. Smoke Generator and Atomizing Nozzle (Royco Mdl. WA or equiv.)
2. DOP - Commercial, Odorless
3. Sinclair-Phoenix Particulate Counter (Mdl. J2000 or equiv.)
4. Thermometer, 0 - 180°F.
5. Relative Humidity Indicator (Bendix-Friez Mdl. 594 or Serdex)
6. Recording Anemometer (Gelman Wallac Md. GGA2C or equiv.)
7. Light Scattering Photometric Particulate Counter
8. General Electric Halogen Leak Detector
9. Gas Chromatograph (Bechman GC-2A or equiv.)
10. Stop Watch
11. Dwyer, Inclined, Vertical Manometer (Model 400 or equiv.)
12. Portable Humidity Indicator, Honeywell (Mdl. 611A or equiv.)
13. Leeds & Northrup Temperature Recorder (or equiv.)
14. Simpson Temp. Meter (Mdl. 388 or equiv.)
15. Simpson Volt Meter (Mdl. 260 or equiv.)
16. Strobe Light - Strobatac, General Radio

D. QUALITY ASSURANCE PROVISIONS

1. All monitoring tests will be witnessed by Quality Assurance.
2. All deviations from the detailed procedures of this plan shall be recorded by the Quality Assurance representative and corrective action shall be taken.
3. Deviations may require that the monitoring cycle be repeated or it may be more effective to continue the monitoring and review the entire data package to determine whether the test needs to be repeated. This decision will be made by facility engineers.
4. All equipment used in the monitoring shall be within its calibration cycle.

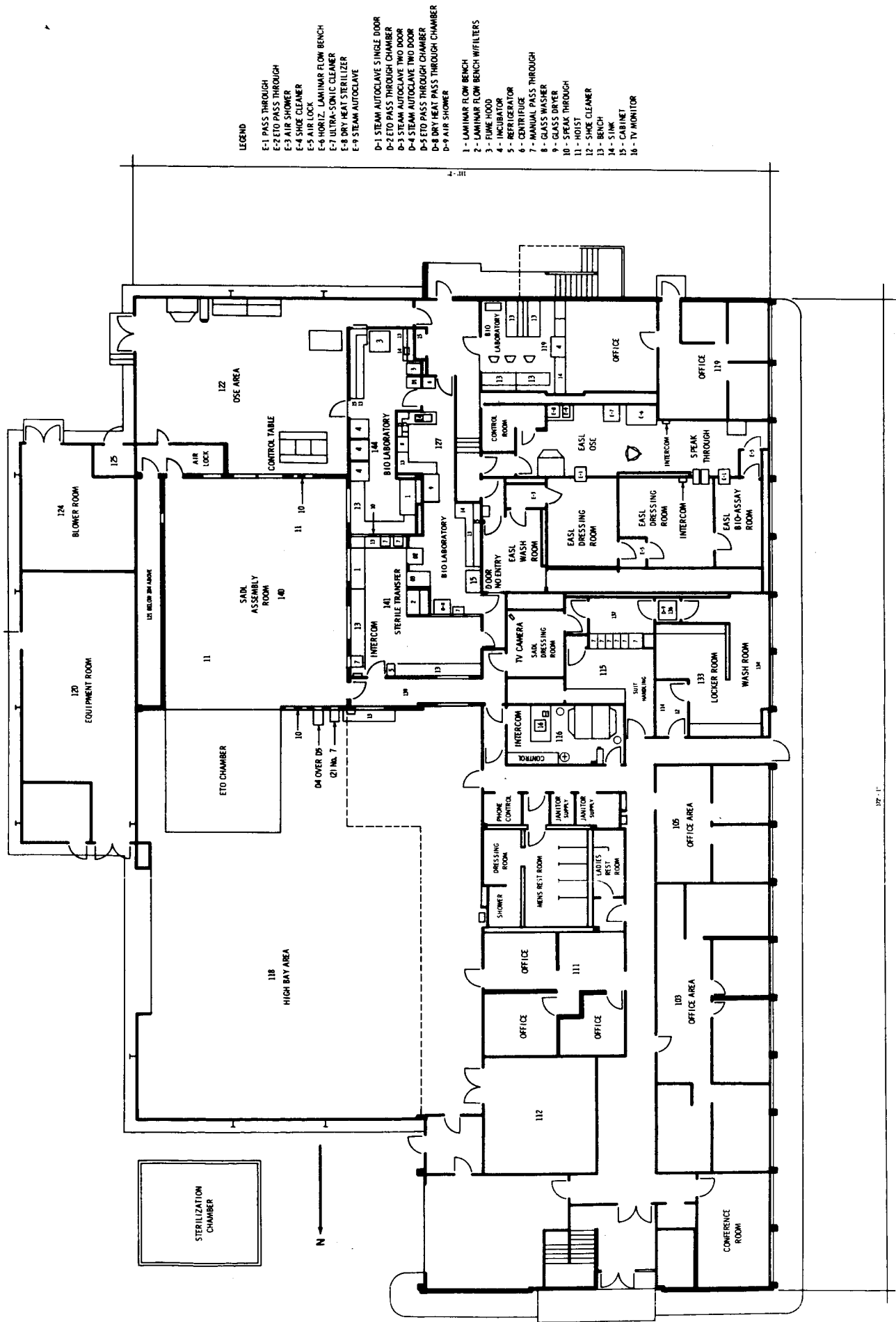


Figure 1. GENERAL LAYOUT OF SACL

E. SADL MONITORING PLAN.

T - Facility Environmental & Support Systems.

1.1 - System AC - 1

1.1.1 - Environmental Control for Assembly Room (Area #140)

1.1.1.1 - Temperature

1.1.1.1.1 - Daily Monitoring Requirements

A - Required 70 °F + 7 °F - 3 °F

B - Instrumentation - Honeywell Recorder

C - Reporting Method - Log high and low daily - if out of specification, report by telephone to plant maintenance for correction.

D - Record time and action requested in Facility Maintenance Log.

1.1.1.1.2 - Weekly Monitoring Requirements

A - Install New Honeywell Recording Chart at beginning of week and file last week's chart in Facility Control file.

1.1.1.1.3 - Monthly Monitoring Requirements

A - Required 70 °F + 7 °F - 3 °F

B - Instrumentation - Friez-Hygro-Thermograph and calibrated thermometer.

C - Record temperature as indicated on an independent shop standard instrument to ensure that the daily recording instruments are recording correctly.

D - Results shall be included in formal monthly report.

1.1.1.2 - Relative Humidity

1.1.1.2.1 - Daily Monitoring Requirements

A - Required 45 % + 0 % - 5 %

- B - Instrumentation - Honeywell Recorder.
- C - Reporting Method - Log high and low daily - if out of specification, report by phone to plant maintenance for correction.
- D - Record time and action requested in Facility Maintenance Log.

1.1.1.2.2 - Weekly Monitoring Requirements

- A - Install new Honeywell control chart at beginning of week and file last week's chart in Facility Control File.

1.1.1.2.3 - Monthly Monitoring Requirements.

- A - Required 45 % + 0 % - 5 %
- B - Instrumentation - Friez-Hygro-Thermograph.
- C - Record relative humidity as indicated on an independent shop standard instrument to ensure that the daily recording instruments are recording correctly.
- D - Results shall be included in formal monthly reports.

1.1.1.3 - Static Pressure

1.1.1.3.1 - Daily Monitoring Requirements

- A - Maintain at 0.4 ^{+ .025} - .0 inches W.G. above atmospheric at all times.
- B - Instrumentation - Magnehelic Static pressure gauges.
- C - Reporting Method - Record static pressure (3) times daily in Facility Control Log. If out of specification, report by phone to plant maintenance for correction.
- D - Record time and action requested in Facility Maintenance Log.

1.1.1.3.2 - Weekly Monitoring Requirements

- A - None Required

1.1.1.3.3 - Monthly Monitoring Requirements

A - Identical to daily monitoring requirements.

B - Results shall be included in formal monthly report.

1.1.1.4 - Air Velocity

1.1.1.4.1 - Daily Monitoring Requirements.

A - None Required

1.1.1.4.2 - Weekly Monitoring Requirements.

A - None Required.

1.1.1.4.3 - Monthly Monitoring Requirements.

A - Required - The air velocity shall be 75 ft. per minute \pm 20 ft. per minute for all areas in the room except for points 12 inches or less from the wall or protuberance.

B - Measurements shall be taken 6 ft. and 25 ft. above the floor.

C - Instrumentation - Gelman-Wallac Anemometer.

D - Reporting Method - Calibrate instrument to manufacturer's instructions and secure readings and record them for each specified location as shown in Appendix -A-.

E - Results shall be included in formal monthly report.

F - Evaluate information and recommend required corrective action.

1.1.1.5 - Non-viable Particulate Count

1.1.1.5.1 - Daily Monitoring Requirements

A - None Required

1.1.1.5.2 - Weekly Monitoring Requirements.

- A - Required - The particle count shall not exceed a total of 100 Particles per cubic foot .5 micron and larger.
- B - Particle count will be taken for a (24) hour period at specified locations as shown in Appendix -A-.
- C - Instrumentation - Light Scattering Photometric Particulate counter (Royco-Md. -PC 220 or equiv.).
- D - Reporting Method - Calibrate machine to manufacturer's instructions and record the readings on the digital read out manually adding the location data after the particle count.

Continue to move the counter over test positions until all areas have been monitored.
- E - Convert the data thus obtained to particles per cubic foot by multiplying the readings obtained by the appropriate factors.
- F - Fill in the data sheet with the total numbers.
- G - Results shall be included in formal monthly report.
- H - Evaluate and recommend corrective action.

1.1.1.5.3 - Monthly Monitoring Requirements

- A - No additional requirement

- 1.1.1.6 - Viable Particulate Count (to be supplied later)
- 1.1.1.7 - Surface Viable Contaminants (to be supplied later)

1.2 - System AC-2

1.2.1 - Environmental control for air lock & sterile transfer room
(Room #139 / #141)

1.2.1.1 - Temperature

1.2.1.1.1 - Daily Monitoring Requirements

A - Required 70 °F + 7 °F - 3 °F.

B - Instrumentation - Honeywell Recorder.

C - Reporting Method - Log high and low daily - If out of specification, report by telephone to plant maintenance for correction.

D - Record time and action requested in Facility Maintenance Log.

1.2.1.1.2 - Weekly monitoring requirements.

A - Install new Honeywell recording chart at beginning of week and file last week's chart in Facility Control File.

1.2.1.1.3 - Monthly Monitoring Requirements.

A - Required 70 °F + 7 °F - 3 °F.

B - Instrumentation - Friez-Hygo-Thermograph and calibrated thermometer.

C - Record temperature as indicated on an independent shop standard instrument to ensure that the daily recording instruments are recording correctly.

D - Results shall be included in formal monthly report.

1.2.1.2 - Relative Humidity

1.2.1.2.1 - Daily Monitoring Requirements.

- A - Required 45 % + 0 % - 5 %.
- B - Instrumentation - Honeywell recorder.
- C - Reporting Method - Log high and low daily - If out of specification, report by phone to plant maintenance for correction.
- D - Record time and action requested in Facility Maintenance Log.

1.2.1.2.2 - Weekly Monitoring Requirements.

- A - Install new Honeywell control chart at beginning of week and file last week's chart in Facility Control File.

1.2.1.2.3 - Monthly Monitoring Requirements.

- A - Required 45% + 0% - 5%.
- B - Instrumentation - Friez-Hygo-Thermograph.
- C - Record relative humidity as indicated on an independent shop standard instrument to ensure that the daily recording instruments are recording correctly.
- D - Results shall be included in formal monthly report.

1.2.1.3 - Static Pressure

1.2.1.3.1 - Daily Monitoring Requirements.

- A - Maintain at 0.25 ^{+ 0.025} - 0.000 inches W.G. above atmospheric at all times in Room #130.
- B - Maintain at 0.30 ^{+ 0.025} - 0.000 inches W.G. above atmospheric at all times in Room #141.
- C - Instrumentation - Magnehelic static pressure gauges.
- D - Reporting method - Record static pressure three (3) times daily in Facility Control Log. If out of specification, report by phone to Plant Maintenance for correction.

E - Record time and action requested in Facility Maintenance Log.

1.2.1.3.2 - Weekly Monitoring Requirements.

A - No additional required over daily.

1.2.1.3.3 - Monthly Monitoring Requirements.

A - Identical to daily monitoring requirements.

B - Results shall be included in formal monthly report.

1.2.1.4 - Air Velocity

1.2.1.4.1 - Daily Monitoring Requirements.

A - No additional requirement

1.2.1.4.2 - Weekly Monitoring Requirements.

A - No additional requirement

1.2.1.4.3 - Monthly Monitoring Requirements.

A - No additional requirement

1.2.1.5 - Non-viable Particulate Count.

1.2.1.5.1 - Daily Monitoring Requirements.

A - No additional requirement

1.2.1.5.2 - Weekly Monitoring Requirements.

A - No additional requirement

1.2.1.5.3 - Monthly Monitoring Requirements.

A - Required - The particle count shall not exceed a total of 10,000 particles per cubic foot .5 micron or larger or 65 particles 5 micron and larger.

B - Particle count will be taken for a (24) hour period at specified locations as shown in Appendix A.

C - Instrumentation - Light scattering Photometric Particulate counter (Royco Mdl. - PC 220 or equiv.).

D - Reporting Method - Calibrate machine to manufacturer's instructions and record the readings on the digital readout, manually adding the location data after the particle count. Continue to move the counter over test positions until all areas have been monitored.

E - Convert the data thus obtained to particles per cubic foot by multiplying the readings obtained by the appropriate factors.

F - Fill in data sheet with the total numbers.

G - Results shall be included in formal monthly report.

H - Evaluate and recommend corrective action.

1.2.1.6 - Viable Particulate Count - (To be supplied later.)

1.2.1.7 - Surface Viable Contaminants - (To be supplied later.)

1.3 - System AC - 3

1.3.1 - Environmental Control for Dressing Room #138.

1.3.1.1 - Temperature

1.3.1.1.1 - Daily Monitoring Requirements

A - Required 70 °F + 7 °F - 3 °F.

B - Instrumentation - Honeywell Recorder.

C - Reporting Method - Log high and low daily - If out of specification, report by telephone to plant maintenance for correction.

D - Record time and action requested in Facility Maintenance Log.

1.3.1.1.2 - Weekly Monitoring Requirements.

A - Install new Honeywell recording chart at beginning of week and file last week's chart in Facility Control File.

1.3.1.1.3 - Monthly Monitoring Requirements.

A - Required 70 °F + 7 °F - 3 °F.

B - Instrumentation - Friez-Hygo-Thermograph and calibrated thermometer.

C - Record temperature as indicated on an independent shop standard instrument to ensure that the daily recording instruments are recording correctly.

D - Results shall be included in formal monthly report.

1.3.1.2 - Relative Humidity

1.3.1.2.1 - Daily Monitoring Requirements.

A - Required 45 % + 0 % - 5 %.

B - Instrumentation - Honeywell recorder.

C - Reporting Method - Log high and low daily - If out of specification report by telephone to Plant Maintenance for correction.

D - Record time and action requested in Facility Maintenance Log.

1.3.1.2.2 - Weekly Monitoring Requirements.

A - Install new Honeywell control chart at beginning of week and file last week's chart in Facility Control File.

1.3.1.2.3 - Monthly Monitoring Requirements.

A - Required 45 % + 0 % - 5 %.

B - Instrumentation - Friez-Hygo-Thermograph.

C - Record relative humidity as indicated on an independent shop standard instrument to ensure that the daily recording instruments are recording correctly.

D - Results shall be included in formal monthly report.

1.3.1.3 - Static Pressure

1.3.1.3.1 - Daily Monitoring Requirements.

A - Maintain at 0.3 \pm $\frac{0.025}{0.000}$ inches W. G. above atmospheric at all times.

B - Instrumentation - Magnehelic static pressure gauges.

C - Reporting Method - Record static pressure (3) times daily in Facility Control Log. If out of specification report by telephone to plant maintenance for correction.

D - Record time and action requested in Facility Maintenance Log.

1.3.1.3.2 - Weekly Monitoring Requirements.

A - No Additional Required Over Daily

1.3.1.3.3 - Monthly Monitoring Requirements.

A - Identical to daily monitoring requirements.

B - Results shall be included in formal monthly report.

1.3.1.4 - Air Velocity

1.3.1.4.1 - Daily Monitoring Requirements.

A - None Required.

1.3.1.4.2 - Weekly Monitoring Requirements.

A - None Required.

1.3.1.4.3 - Monthly Monitoring Requirements.

A - Required - The air velocity shall be 100 ft. per. minute \pm 20 ft. per. minute for all areas in the room except for points 24 inches from the walls, filters, or protuberance.

B - Measurements shall be taken at specified locations as shown in Appendix -A-.

C - Instrumentation - Gelman-Wallac Anemometer.

D - Reporting Method - Calibrate instrument to manufacturer's instructions and secure readings and record them for each specified location.

E - Results shall be included in formal monthly report.

F - Evaluate information and recommend required corrective action.

1.3.1.5 - Non-viable Particulate Count

1.3.1.5.1 - Daily Monitoring Requirements.

A - None Required.

1.3.1.5.2 - Weekly Monitoring Requirements

A - None Required

1.3.1.5.3 - Monthly Monitoring Requirements.

- A - Required - The particle count shall not exceed a total of 100 particles per cubic foot .5 microns and larger.
- B - Particle count will be taken for a (24) hour period at specified locations as shown in Appendix -A-.
- C - Instrumentation - Light scattering photometric particulate counter (Royco-MDL-PC 220 or equiv.).
- D - Reporting Method - Calibrate machine to manufacturer's instructions and record the readings on the digital readout, manually adding the location data after the particle count.

Continue to move the counter over test positions until all areas have been monitored.
- E - Convert the Data thus obtained to particles per cubic foot by multiplying the readings obtained by the appropriate factors.
- F - Fill in the data sheet with the total numbers.
- G - Results shall be included in formal monthly report.
- H - Evaluate and recommend corrective action.

1.3.1.6 - Viable Particulate Count. (To be supplied later.)

1.3.1.7 - Surface Viable Contaminants. (To be supplied later.)

1.4 - System AC - 4

1.4.1 - Environmental Control for Bio-lab - Room #127-#144.

1.4.1.1 - Temperature

1.4.1.1.1 - Daily Monitoring Requirements

A - Required 72 °F + 5 °F - 5 °F.

B - Instrumentation - Honeywell Recorder.

C - Reporting Method - Log high and low daily. If out of specification, report by telephone to plant maintenance for correction.

D - Record time and action requested in Facility Maintenance Log.

1.4.1.2 - Relative Humidity.

1.4.1.2.1 - Daily Monitoring Requirements.

A - Required 45 % + 5 % - 5 %.

B - Instrumentation - Honeywell Recorder.

C - Reporting Method - Log high and low daily. If out of specification, report by telephone to plant maintenance for correction.

D - Record time and action requested in Facility Maintenance Log.

1.4.1.3 - Relative Humidity and Temperature.

1.4.1.3.1 - Weekly Monitoring Requirements.

A - Install new Honeywell control chart at beginning of week and file last week's chart in Facility Control File.

1.5 - Monitoring of EASL System

- 1.5.1 - The following are the requirements for the EASL facility under JPL Specification XOY-50543-GEN, with revisions recommended by AVCO as of August, 1967.

I. SCOPE

1.1 This specification establishes the requirements that shall be met and maintained within the Experimental Assembly Sterilization Laboratory (EASL).

2. APPLICABLE DOCUMENTS

2.1 The following documents form a part of this specification to the extent specified herein:

SPECIFICATIONS AND PROCEDURES

Jet Propulsion Laboratory

GMO - 50470 - GEN-A

General Specifications Microbiological
Certification of Spacecraft Hardware
Sterility

Sandia Corporation

SG 17859

Leak Testing of HEPA Filter
Installations in Laminar Flow
Clean Rooms

NASA Headquarters

Preliminary Standard Procedures
for the Microbiological Evaluation
of Spacecraft Hardware

Jet Propulsion Laboratory

EASL 300.01

EASL Microbiological Assy and
Certification of Spacecraft Hardware
Sterility

Federal

FED. STD. 209a

Clean Room and Clean Work Station
Requirement, Controlled Environment.

3. REQUIREMENTS

3.1 Conflicting requirements. In case of conflict between the requirements of this specification and any other document referenced herein, the requirements of this specification shall govern.

3.2 Request for deviation. Any change from the requirements of this specification, or applicable documents listed herein, shall be considered a deviation. Request for a deviation shall be submitted in writing to the EASL facility operator for consideration and consent.

3.3 Certification period. The certification period shall continue for a period of three consecutive days.

3.4 Microbial levels and parametric measurements. Assaying and monitoring techniques shall include microbiological and total particulate samplings and parametric measurements. Monitoring routines shall demonstrate the reliability of the facility to conform to the requirements specified in Table I.

3.5 Certification. Monitoring routines shall provide constant surveillance of the facility throughout each phase of operational activity. At monthly intervals, the facility shall be recertified as to its ability to meet the requirements stated in Table 1. If the EASL facility has been operational for periods in excess of the monthly recertification requirement, the monitoring data accumulated throughout the operational period may be used for recertification. If EASL has been inactive, the recertification requirements shall be waived until operational activity is resumed, however, immediately prior to that time recertification must be established.

3.6 Methods of assay.

3.6.1 Microbiological monitoring.

3.6.1.1 Air Ventilation inlet air and room air shall be assayed not less than twice during each day of the certification periods.

The technique of Sample Processing shall be as defined in EASL 300.01 and Preliminary NASA Standard Procedures for the Microbiological Evaluation of Spacecraft Hardware. Reynier Slit Air Samplers shall be used to sample intramural air and vented air. Ventilation inlet air and room air shall be sampled at sites 1, 2, 3 and 4, see Figure 1. Each sample taken by the Reynier Air Sampler shall be of a one hour duration.

3.6.1.2 Surfaces. The degree of microbial contamination accumulating on surfaces within the bioclean room shall be assayed each day of the certification period. The techniques of sample processing shall be in accordance with EASL 300.01 and Preliminary NASA Standard Procedures for the Microbiological Evaluation of Spacecraft Hardware.

Stainless Steel strip fallout collectors shall be used at sites 1, 2, 3 and 4. See Figure 1. Six stainless steel fallout collector strips per site will be assayed after 24, 48 and 72 hours exposures to the EASL environment. The strips will be aseptically collected, placed individually in sterile containers and processed.

Rodac impressions shall be made at the sites designated in Figure 2. After the Rodac plates have been used they should be incubated within one hour.

3.6.2 Total airborne particulate monitoring. Particle monitoring shall be done once each day per site of the certification period using ROYCO particle counter. Site sampling shall be made at the locations indicated on

Figure 3. Each location shall be a 3-cubic foot sample. (30 minutes per location).

3.6.3 Record of parametric measurements.

3.6.3.1 Ventilation

3.6.3.1.1 Temperature. Temperature of the bioclean room shall be recorded continuously during the certification period on the temperature recorder/controller and in addition shall be measured (manually) and recorded at locations shown on Figure 4 once daily.

3.6.3.1.2 Relative Humidity. Relative humidity of the laminar down-flow room shall be recorded continuously during the certification period on the recorder/controller and in addition shall be measured (manually) and recorded at the locations shown on Figure 4 once daily.

3.6.3.1.3 Air pressure differential. Differential positive air pressure, based on the pressure outside the bioclean area, shall be recorded three times each day of the certification period.

3.6.3.1.4 Air Velocity. Air velocity shall be measured once daily during the certification period at locations shown on Figure 5.

3.6.4 Measurements of Laminar Flow Dressing Room shall be made concurrently with the testing in the Assembly Room.

3.6.4.1 Airborne Particulate Measurements. Particle monitoring shall be made once daily at the locations noted on Figure 6. Each location shall be a 3-cubic foot sample (30 minutes).

3.6.4.2 Air Temperature Measurements. Record the temperature at the locations shown on Figure 7 once a day of the certification period.

3.6.4.3 Relative Humidity Measurements. Record the relative humidity at the locations shown on Figure 7 each day of the certification period.

3.6.4.4 Air Pressure Measurements. Record the air pressure three times each day of the certification period.

3.6.4.5 Air Velocity Measurements. Monitor and record the air velocity once a day during the certification period at the locations shown on Figure 6, and in a horizontal plane 41 inches from the ceiling.

3.7 Leak testing filters. Each filter shall be tested for leaks in accordance with the procedure specified in Sandia Specification SG 17859. This test will be made annually, or when over evidence of possible filter leakage occurs.

4. QUALITY ASSURANCE PROVISIONS

4.1 Surveillance. JPL Quality Assurance shall witness the tests specified in Table I to verify that they are conducted in the prescribed method, manner, frequency and area.

4.2 Calibration. Equipment specified in the procedures shall be of current calibration as evidenced by a calibration sticker.

4.3 Measurements. All measurements taken in EASL, based on the requirements of Table I, shall be maintained in a permanent record.

5. CERTIFICATION

5.1 Certification report. Each certification report shall be approved and signed by the facility operator, the cognizant quality assurance representative, the cognizant microbiologist, and the capsule sterilization engineer.

Table I. Summary of the Certification Requirements
for Laminar Downflow Rooms

Item to be sampled or measured	Requirement
Ventilation inlet air - microbial	Not to exceed an average of one viable particle per cubic foot of inlet air in any two successive samples of 120 cubic feet.
Intramural air - microbial	Not to exceed an average of two viable particles per cubic foot of air for any two successive samples of 120 cubic feet.
Intramural air - total particle	Not to exceed a contamination level of more than 100 particles 0.5 micron or lar- ger and no particles 5.0 microns per cubic foot throughout the certification period.
Microbial contamination of surfaces	Not to exceed an average of 200 viable microorganisms per square foot of surface throughout the certification period.
Temperature	70°F + 7° - 3°
Relative humidity	45%, +0, -5% at all temperatures.
Air pressure	Must maintain highest positive pressure minimum of 0.05 in W. G. pressure differential over all other pressurized or nonpressurized environments.
Air velocity	75 ft/min minimum*
	*Deviation from fed. std. 209A

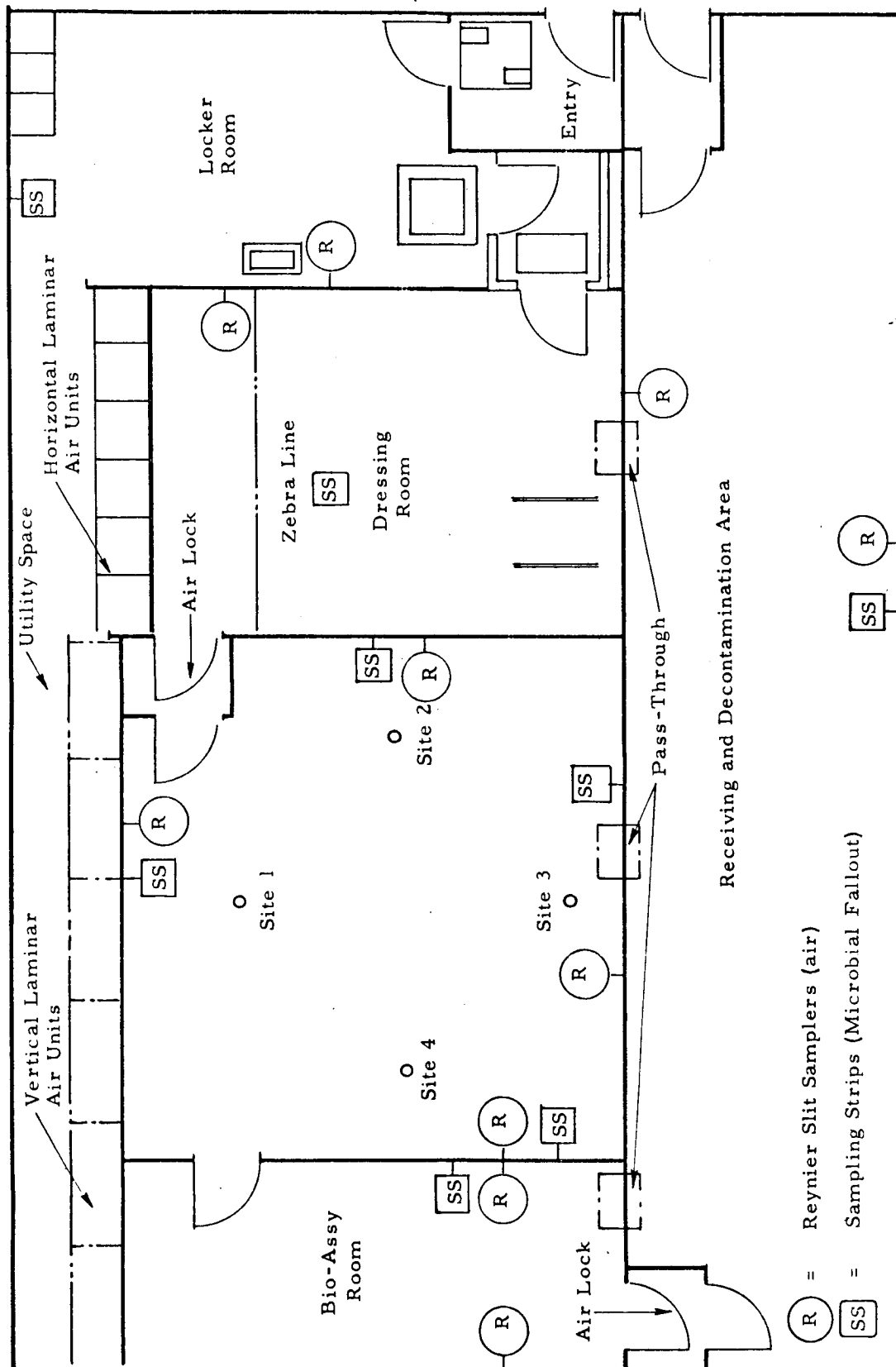


Figure 1. Location of Monitoring Sites Within the EASL Facility

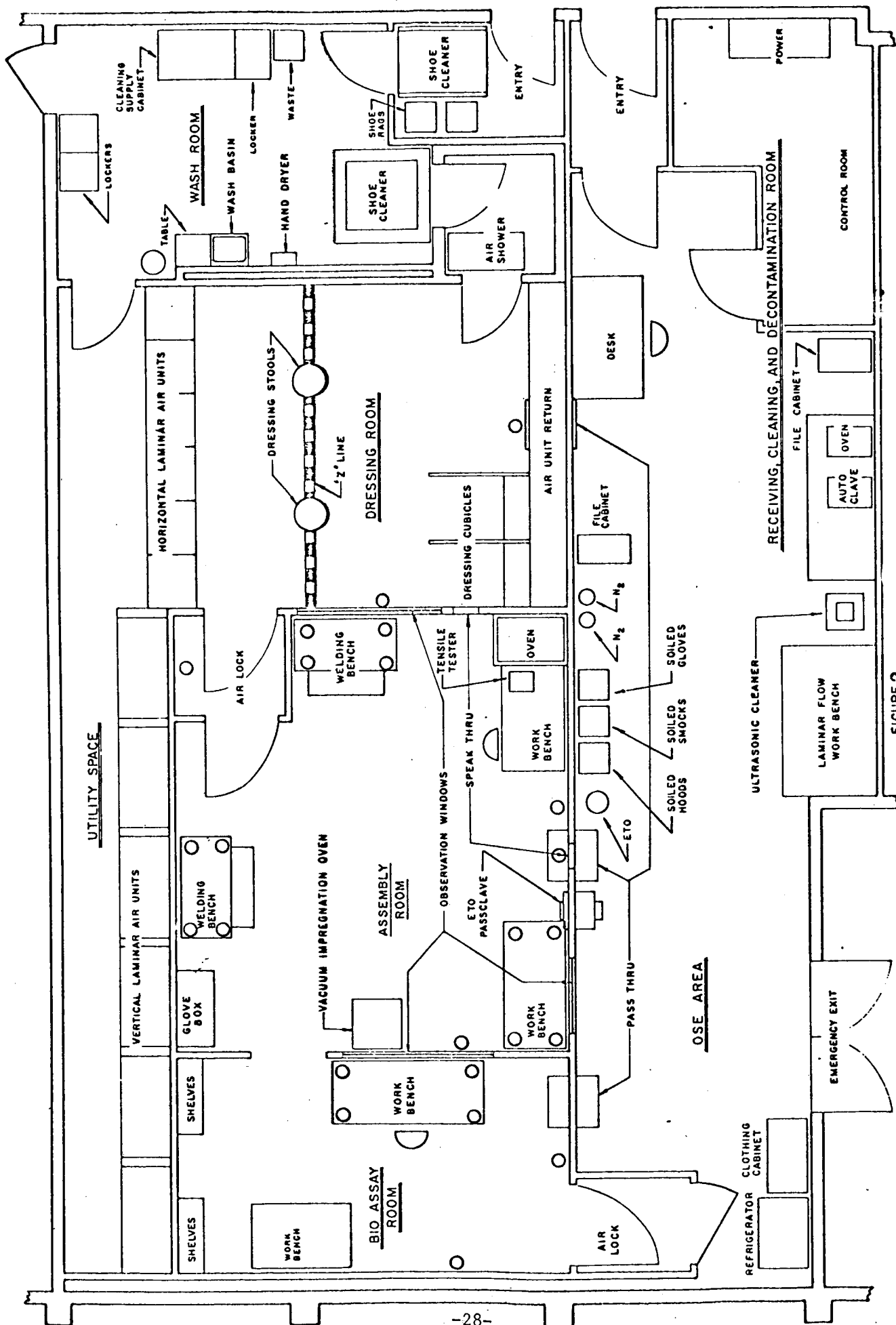


FIGURE 2

Sites for EASL Certification

○ = Sampling Sites

BIO ASSAY ROOM

ASSEMBLY ROOM

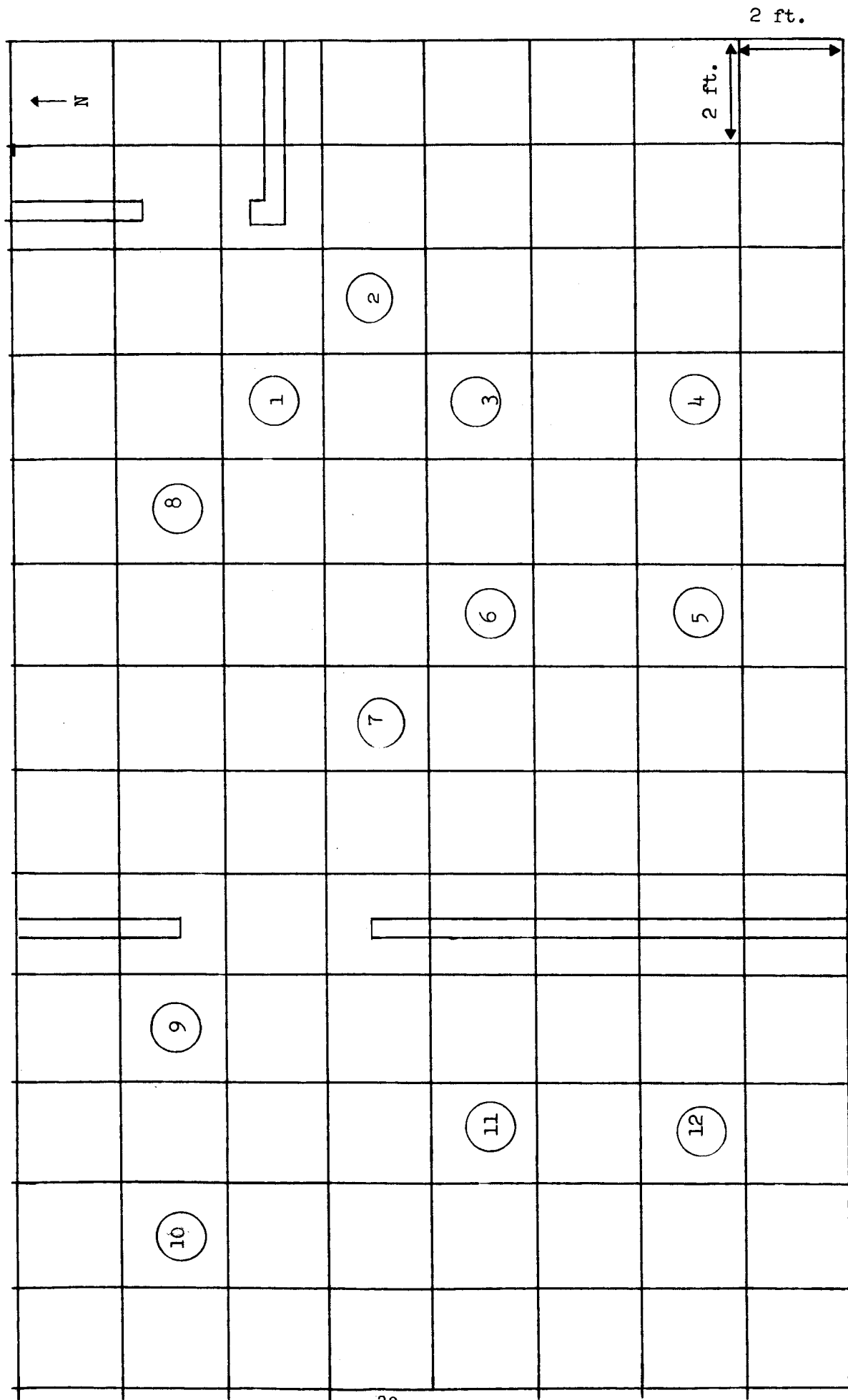


FIGURE 3 LOCATIONS OF PARTICLE COUNT SITES IN ASSEMBLY AND BIO ASSAY AREAS OF EAST

BIO ASSAY AREA

ASSEMBLY AREA

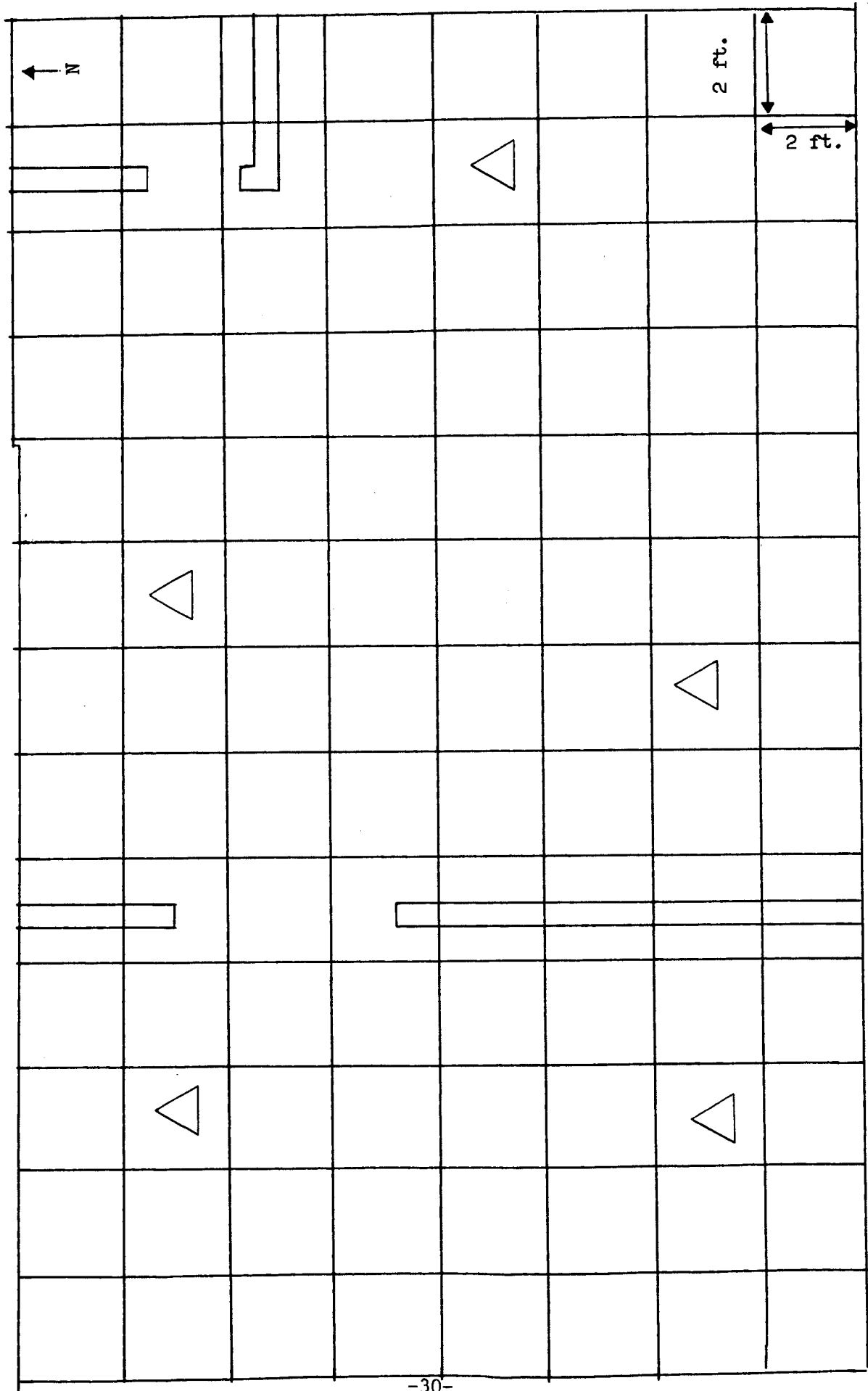


FIGURE 4 LOCATIONS FOR TEMPERATURE AND HUMIDITY MEASUREMENTS IN ASSEMBLY AND BIO ASSAY AREAS OF EAST

BIO ASSAY AREA

ASSEMBLY AREA

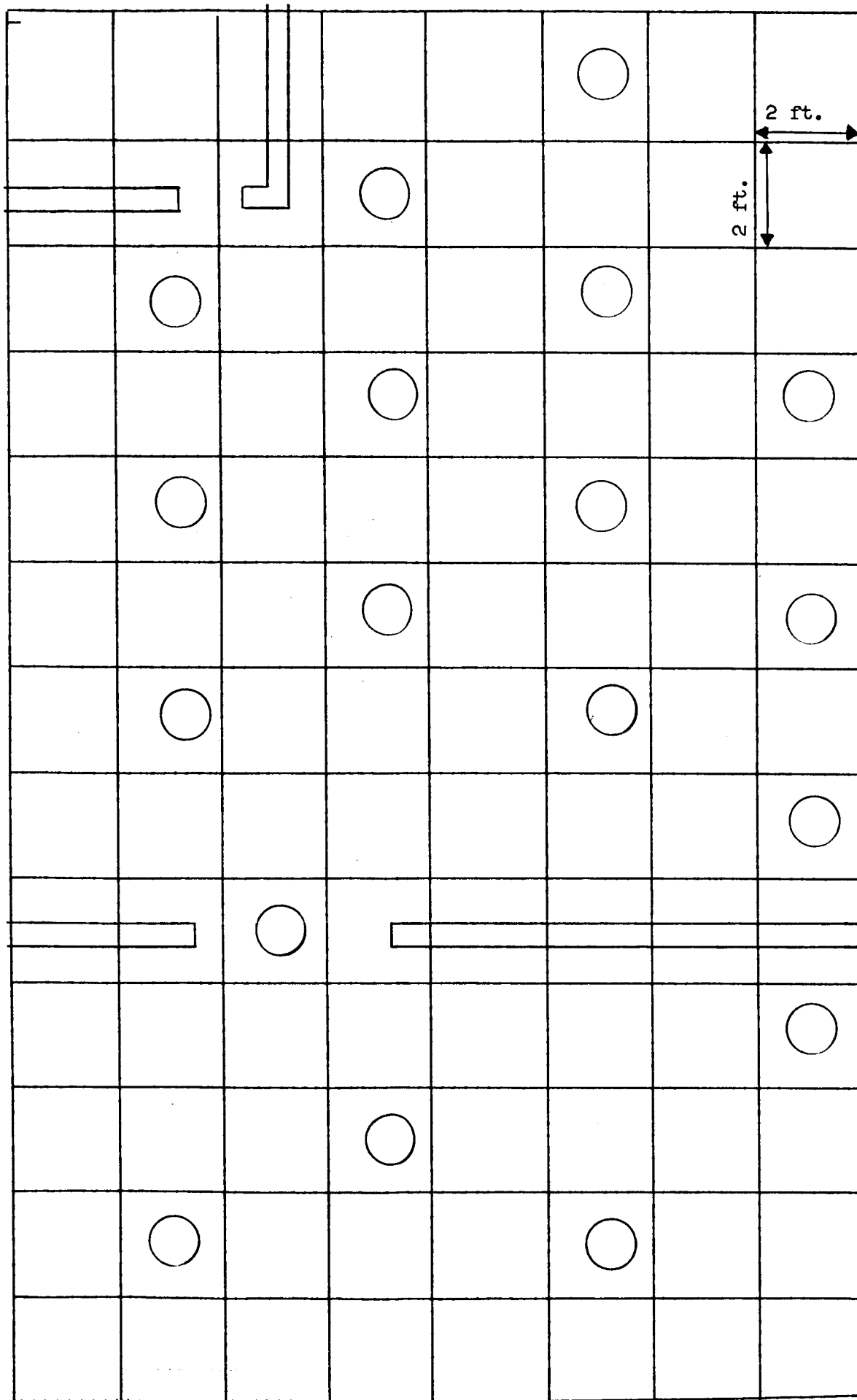


FIGURE 5 LOCATIONS FOR AIR VELOCITY MEASUREMENTS IN THE ASSEMBLY AND BIO ASSAY AREAS OF EAST

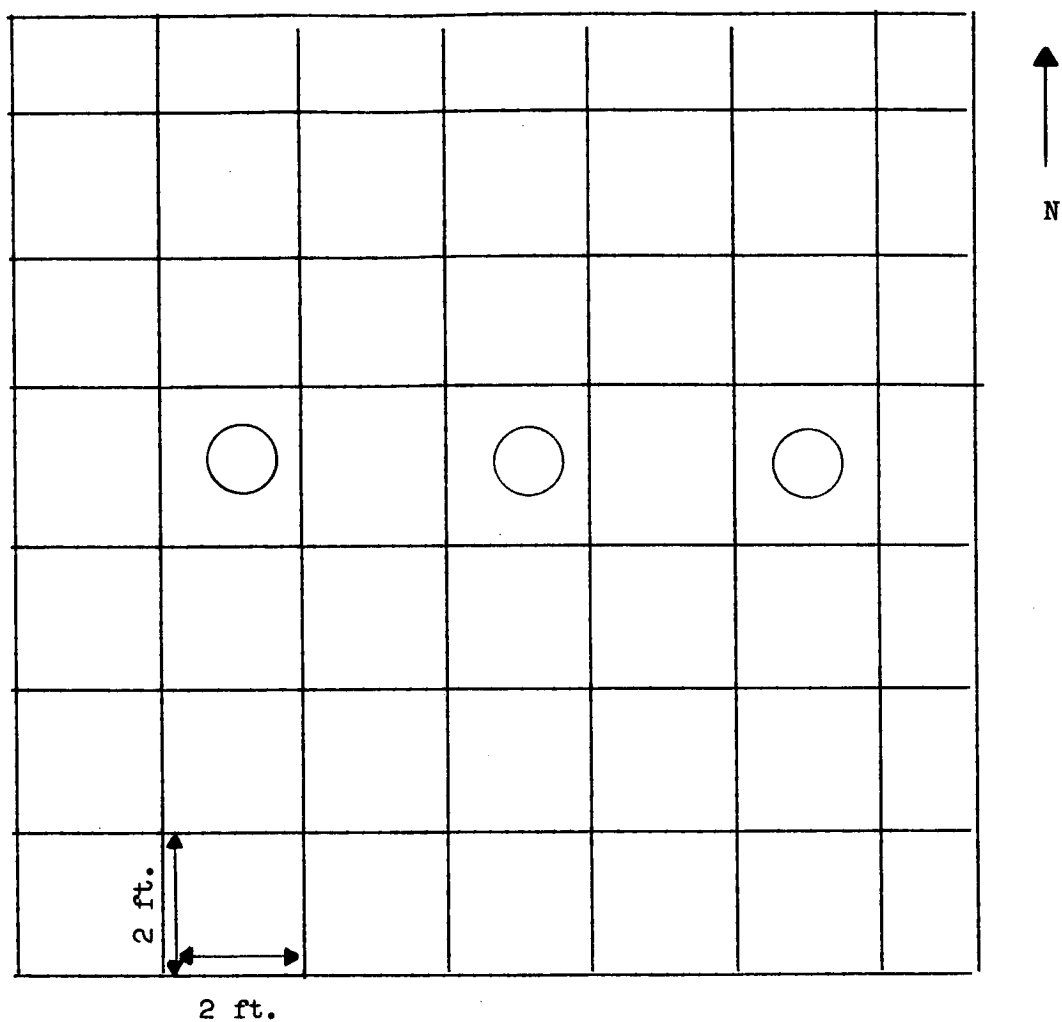


FIGURE 6

EASL DRESSING ROOM LOCATIONS FOR AIR VELOCITY AND PARTICLE
COUNTING MEASUREMENTS

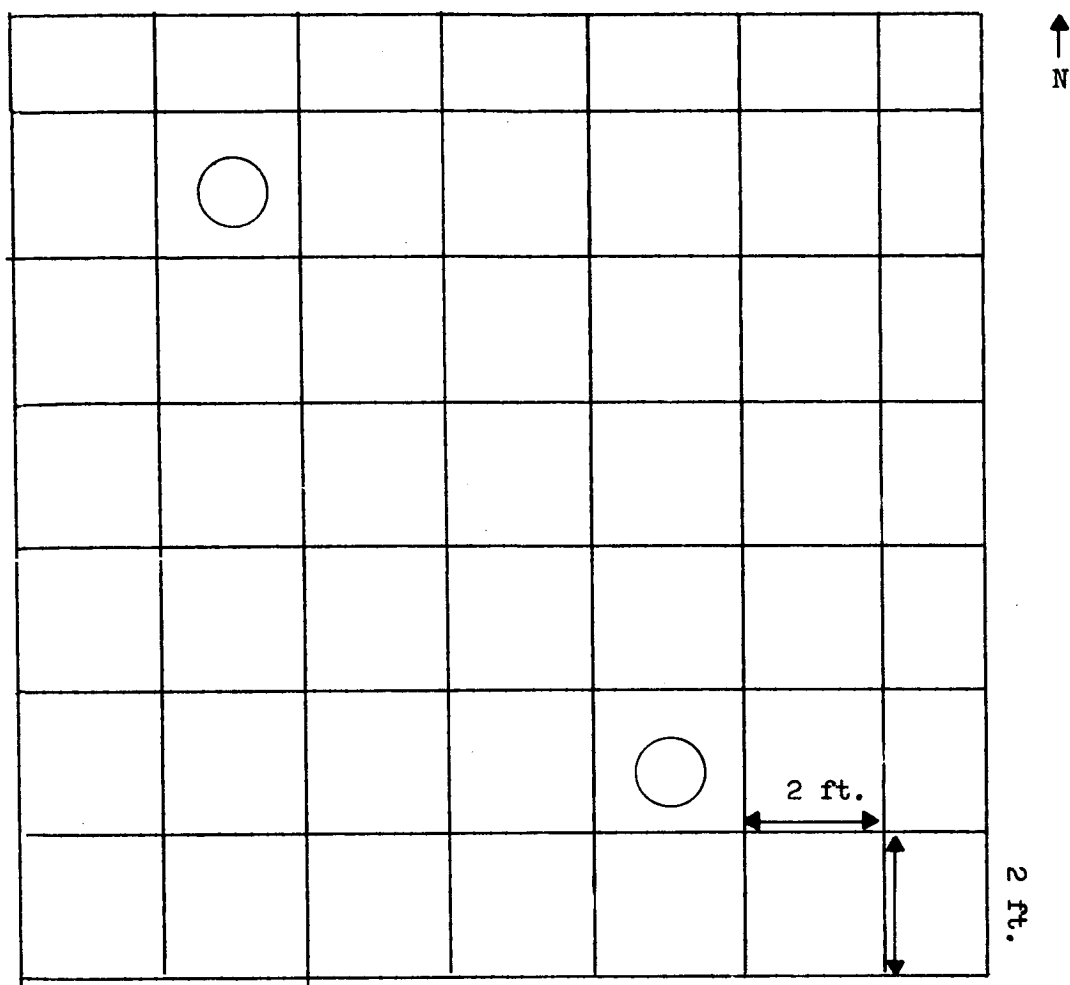


FIGURE 7 EASL DRESSING ROOM LOCATIONS FOR AIR TEMPERATURE AND HUMIDITY MEASUREMENTS.

1.6 - Other Support Systems.

1.6.1 - Distilled Water System

1.6.1.1 - Daily Monitoring Requirements

A - Inspect sight glass on storage tank at the beginning of each day to ensure an adequate supply is on hand.

B - Red warning light on Honeywell control panel located in Facility Control Room indicates water is at its minimum operating level and water should be ordered immediately.

1.6.2 - House Vacuum System

1.6.2.1 - Daily Monitoring Requirements

A - Ensure at the end of working day the system is shut down.

B - System can be operated from Honeywell control panel in Facility Control Room.

1.6.2.2 - Weekly Monitoring Requirements.

A - System collecting bag located in Mechanical Equipment Room 124, should be shaken down once a week.

1.6.2.3 - Monthly Monitoring Requirements.

A - Collection tank should be dumped and cleaned.

1.7 - Personnel Monitoring Control

1.7.1 - Monitoring Requirements for Personnel Entering the SADL Facility.

- A - Each person will sign in and out of the facility. The time of entry and departure will be recorded in the visitor log book located in Facility Control.
- B - All personnel will be monitored by a quality assurance representative through the cleaning cycle before entry into the facility. All procedures as posted in the wash room will be carried out.
- C - Any violations will be recorded by quality assurance representative and corrective action will be taken.

1.7.2 - Key Control

- A - Keys to SADL and EASL facility are issued by Locks and Keys. Only personnel whose job classification requires it, have keys to these areas.
- B - Custodians and guards have admittance only by securing the keys from the guard office.
- C - Emergency keys exist at all exits of SADL and EASL Facility. Keys are located in a box with breakable glass and in an emergency, access may be gained by using these keys.

1.8 "HEPA" Filters:

1.8.1 Monitoring requirements of "HEPA" Filters.

1.8.1.1 The "HEPA" Filter shall be leak-checked once every 18 months by the performance of a standard "smoke" or "dop" test, or more frequently if the situation so dictates.

1.8.1.2 Equipment required:

1.8.1.2.1 Smoke generator and atomizing nozzle, Royco model WA, 18 CFM maximum capacity 0.3 micron and smaller particle size.

1.8.1.2.2 Photometer, Sinclair Phoenix Particulate Counter, model U2000.

1.8.1.3 Conducting test:

1.8.1.3.1 The portable smoke generator shall be started and the required smoke concentration, for 100% deflection of the aerosol photometer ($4.0 \pm 10\%$ on the Logarithmic Scale), introduced into the plenum upstream of the absolute filter.

1.8.1.3.2 The entire downstream surface area of the absolute filter and all seals will be scanned with the photometer probe.

1.8.1.3.3 Mark any areas that leak.

1.8.1.3.4 Repair the leak with RTV Silicone Rubber and scan the filter again, repeating the operation until no leaks occur in the filter.

- 1.8.1.3.5 When all photometer readings are within the allowable leakage rate the maximum reading noted shall be recorded.
- 1.8.1.3.6 Any filter assembly requiring repairs on more than five percent of its surface shall be removed and replaced.
- 1.8.1.3.7 Fill in the Data Sheet for monitoring requirements of filter bank.
- 1.8.1.3.8 The requirements of Section 1.8 thru 1.8.1.3.7 will be performed on all filters in Room #140 - #138 of SADL, and the dressing and bio-assembly rooms of EASL (#118).
(See Room Layouts in Appendix -A-.)

II. Lab Equipment

2.1 - ETO Decontamination Chamber.

2.1.1 - Monitoring Requirements.

2.1.1.1 - To be written after initial certification.

(Reference Test Procedure 6.5.1)

2.2 - Terminal Sterilization Chamber

2.2.1 - Monitoring Requirements

2.2.1.1 - To be written after initial certification.

(Reference Test Procedure 6.5.2)

2.3 - Multiple Sensing Stations (SADL)

2.3.1 - Monitoring of ETO

- 2.3.1.1 - During non-operation the sensing station will constantly monitor the inner chamber to ensure that the ethylene oxide does not enter the chamber through personnel error or valve failure.
- 2.3.1.2 - When the chamber is in operation alarm lights will continuously signal a low oxygen level in the ETO chamber.
- 2.3.1.3 - Monitor the ETO storage tank pressure daily to ensure that the tank is not leaking. In event of a pressure drop during periods of non-use, a system probe by General Electric halogen leak detector will be used.

2.4 - Oxygen Sensing Stations

2.4.1 - Monitoring of Oxygen.

- 2.4.1.1 - Oxygen level in the Assembly Room #140 and Bio-lab #144-127 will be continuously monitored by an audible and signal alarm.
- 2.4.1.2 - Any low level alarms will be noted by memo to all group leaders for information and review.

2.5 - Single Door Steam Sterilizer (D-1)

2.5.1 - Monitoring Requirements.

2.5.1.1 - Once every (6) months the requirements of test procedure (7.5.3) will be met. (See Appendix -A-)

2.5.1.2 - Results will be included in a formal report.

2.6 - ETO Decontamination Chamber (D-2) and (D-5)

2.6.1 - Monitoring Requirements.

2.6.1.1 - Once every (6) months the requirements of test procedure (7.5.4) will be met. (See Appendix -A-)

2.6.1.2 - Results will be included in a formal report.

2.7 - Two Door Steam Sterilizer (D-3) and (D-4)

2.7.1 - Monitoring Requirements.

2.7.1.1 - Once every (6) months the requirements of test procedure (7.5.5) will be met. (See Appendix -A-)

2.7.1.2 - Results will be included in a formal report.

2.8 Two Ton Electric Hoist.

2.8.1 - Monitoring Requirements.

2.8.1.1 - Once every 12 months the requirements of test procedures (7.5.6) will be met. (See Appendix -A-)

2.8.1.2 - Results will be included in a formal report.

2.9 - Two Door Dry Heat Sterilizer.

2.9.1 - Monitoring Requirements.

2.9.1.1 - Once every (6) months the requirements of test procedure (7.5.7) will be met. (See Appendix -A-)

2.9.1.2 - Results will be included in a formal report.

2.10 - Glass Dryer.

2.10.1 - Monitoring Requirements.

2.10.1.1 - Once every (6) months the requirements of test procedure (7.5.8) will be met. (See Appendix -A-)

2.10.1.2 - Results will be included in a formal report.

2.11 - High Speed Refrigerated Centrifuge.

2.11.1 - Monitoring Requirements.

2.11.1.1 - Once every (6) months the requirements of test procedure (7.5.9) will be met. (See Appendix -A-)

2.11.1.2 - Results will be included in a formal report.

2.12 - Incubator, Humidity Controlled

2.12.1 - Monitoring Requirements.

2.12.1.1 - Once every (6) months the requirements of test procedure (7.5.10) will be met. (See Appendix -A-)

2.13 - Laminar Flow Bench (Baker Edgegard Hood)

2.13.1 - Monitoring Requirements.

2.13.1.1 - Once every (6) months the requirements of test procedure (7.5.11) will be met. (See Appendix -A-)

2.13.1.2 - Results will be included in a formal report.

2.14 - Laboratory Glassware Washer

2.14.1 - Monitoring Requirements.

2.14.1.1 - Once every (6) months the requirements of test procedure (7.5.12) will be met. (See Appendix -A-)

2.14.1.2 - Results will be included in a formal report.

2.15 - Refrigerator

2.15.1 - Monitoring Requirements.

2.15.1.1 - Once every (6) months the requirements of test procedure (7.5.15) will be met. (See Appendix -A-)

2.15.1.2 - Results will be included in a formal report.

2.16 - Fume Hood

2.16.1 - Monitoring Requirements.

2.16.1.1 - Once every (6) months the requirements of test procedure (7.5.16) will be met. (See Appendix -A-)

2.16.1.2 - Results will be included in a formal report.

2.17 - Laminar Flow Benches (Pure-air horizontal flow)

2.17.1 - Monitoring Requirements.

2.17.1.1 - Once every (6) months the requirements of test procedure (7.5.17) will be met. (See Appendix -A-)

2.17.1.2 - Results will be included in a formal report.

APPENDIX - "A"

TEST REQUIREMENTS AND
DETAILED TEST PROCEDURES (COMBINED)

6.5.3 Single Door Steam Sterilizer (D-1)

6.5.3.1 The Castle model D-16 162-222 Manual Sterilizer is designed to provide a complete sterilizing cycle.

6.5.3.1.1 The Castle dual lock safety pressure door is a safety device that will prevent opening of the door until the chamber pressure drops to 1-1/2 - 3 P.S.I.

6.5.3.1.2 The pressure regulating valve shall regulate the pressure in the sterilizing cycle. This pressure regulation is pre-set at either 15 or 27 P.S.I.

6.5.3.2 The Castle centigrade and fahrenheit combination dial thermometer shall provide an accurate indication of interior temperature (to 5%) during operation.

6.5.3.3 Temperature, vacuum and pressure recorder shall provide a permanent record of the sterilizing cycle, accurate to within one scale division of the other gauges.

6.5.3.4 Pressure gauges shall indicate the accurate jacket and chamber pressure of the sterilizer during operation to \pm 1.5 P.S.I.

6.5.3.5 The unit shall meet the requirements of the vendor specifications.

7.5.3 Single Door Steam Sterilizer

7.5.3.1 Obtain a copy of the vendor's operating instructions before operating sterilizer and conducting tests.

7.5.3.2 Pressure Gauge Check

If the pointer shows a pressure or vacuum reading when there is positively no pressure or vacuum in the chamber, unscrew the rim from the face of the gauge. Hold the pointer and turn the screw labeled recalibrate, opposite to which the pointer is to be moved, then release pointer. Repeat above slowly until pointer stands at zero position. This device will by no means assure recalibration of the gauges, it is used to re-set the pointer when it has drifted. Pointer re-set devices are only one part of recalibration.

7.5.3.3 The Castle centigrade and fahrenheit combination dial thermometer will be checked against a standard thermometer or temperature indicator such as the Simpson meter.* An adjustment screw is located in the center of the pointer.

7.5.3.4 Temperature, Vacuum and Pressure Recorder

This instrument indicates and records but does not control. During operations of sterilizer observe recorder operation and compare chart readings with pressure gauges and dial thermometer. Adjustments screws for pens are located on the face panel of the recorder and are color coded to agree with pens. Accuracy is one division on chart paper.

*Model 388

7.5.3.5 Check adjustments of pressure lock by building 5 to 8 pounds steam pressure in the chamber.

NOTE: There shall be $(1/32 - 1/16)$ clearance between the ratchet teeth or the door cannot be opened at atmospheric pressure. Vent the sterilizer slowly and try to turn the hand wheel to open the door as the pressure drops. Door shall remain locked until pressure drops to $1-1/2 - 3$ P.S.I. If door opens above 3 P.S.I. turn actuating rod clockwise by loosening nut on rod and if below $1-1/2$ P.S.I., turn rod clockwise. After completing adjustment turn locknut tightly against the bottom ratchet.

7.5.3.6 Locking Bar Adjustment Check

All locking bars shall engage the headring at about the same time that the hand wheel is turned clockwise to seal the door. If not properly adjusted steam will escape from the door gasket that is not being compressed.

If steam escapes, keep door closed and locked, then turn hand wheel slowly clockwise and check the locking bars until they begin to tighten. Remove shims under bars that tighten to soon and add to those that are loose.

6.5.4 ETO Decontamination Chamber (D-2) And (D-5)

6.5.4.1 The Castle Sterox-O-Matic system is designed for effective gas sterilization of heat and steam sensitive materials and assemblies. These units are furnished with an atmospheric or condenser vent.

6.5.4.2 Certification Requirements

6.5.4.2.1 The Sterilock Interlocking Door will permit opening of only one door at a time. Either door will be opened when the opposite door is closed and locked. An emergency operation will allow either door to be opened when the other door is opened.

6.5.4.2.2 The vacuum pump shall remove air and gases from the chamber. It shall draw a vacuum of 23-25 in. of mercury in the chamber. This will be indicated by the certified pressure gauge.

6.5.4.2.3 The recorder shall provide a permanent record of the temperature, pressure and exposure time of each sterilizing cycle.

6.5.4.2.4 The exposure timer will control the period of time that the sterilizer contents are exposed to gas.

6.5.4.2.5 Humidity control in Model 1630 sterilizers will admit pulses of steam into the chamber for 15 minutes. This will be followed by a 15-minute dwell period to permit humidity penetration of the load.

6.5.4.2.6 Pressure gauges shall indicate the accurate chamber and gas cylinder pressures to ± 1.5 psi.

6.5.4.2.7 The unit shall meet the requirements of the vendor specification.

7.5.4 ETO Decontamination Chamber (D-2 and D-5)

7.5.4.1 Obtain a copy of the Manufacturer's Operating Manual and become familiar with its contents before operating and conducting checks.

7.5.4.2 Sterilock Interlocking Door check.

The interlocking door will permit opening of only one door at a time. Either door will be opened when the opposite door is closed and locked. Turn the door lock timer to "ON" and open the door when opposite door is locked. An emergency check will be made which allows either door to be opened when opposite door is opened. Depress emergency door button and open the door.

7.5.4.2.1 Locking bar adjustment check

All locking bars should engage the head ring at the same time when the handwheel is turned clockwise until the door is sealed. If steam escapes from gasket, adjustments must be made. Engage locking bars and turn handwheel slowly clockwise and check the tightening of the bars. Remove shims from under bars that tighten too soon and add to those that are loose. When closing and tightening the sterilizing door, after approximately four turns of the handwheel, a door locking bar engages the door switch to start the cycle. Continue to tighten door a few more turns to insure complete sealing of the door gasket.

7.5.4.3 Vacuum Pump Operational Check

The Vacuum Pump must pull 23-25 inches of vacuum in less than 5 minutes. Check with stop watch. If pump fails requirements, refer to preventive maintenance procedure on Castle Sterox-O-Matic Gas Sterilizer under vacuum pump.

7.5.4.4 Temperature, Pressure Recorder

This instrument indicates and records but does not control. During a sterilizing cycle observe chart readings with chamber pressure gauge and chamber temperature gauge. Adjustments screws for pens are located on the face of the recorder behind the door and are color coded to agree with pens.

NOTE: The temperature gauge will agree with the recorder after the temperature has stabilized for one hour. On temperature rise or fall, the dial thermometer will lag or lead the pen recorder temperature by eight or ten degrees.

7.5.4.5 Pressure and Temperature Gauges

The pressure gauges shall have been calibrated previous to the operational check of the chamber, and a calibration sticker adhered to them. The temperature gauge (dial thermometer) will be checked and adjusted if necessary against a certified temperature indicator-recorder. An adjustment screw is located in the center of the pointer.

NOTE: During the humidification phase, the temperature indicators may give erratic readings due to the vacuum, and water vaporization. The temperature gauge will agree with the recorder after the temperature has stabilized for one hour. On temperature rise or fall, the dial thermometer will lag or lead the pen recorder by eight or ten degrees. The load-unload and install gas cylinder pilot lights will be lit.

7.5.4.6 Exposure Timer Check

If the exposure time indicated on the recorder chart does not agree with the time setting, loosen the two set screws in the pointer and adjust it to snap-off at the off position. When re-tightening the screws allow 1/16 inch clearance between the pointer and the stops.

Adjust the middle pressure switch J-67 if necessary in the control box to energize the exposure timer when the chamber pressure reaches 8 psig in a low pressure unit and 25 psig in a high pressure unit.

7.5.4.7 Humidity Control Check(Model 1630 Sterilizer)

The Castle Gas Sterilizer Model 1630 uses a humidity indicator-control for remote reading of relative humidity in the chamber. A sensing element is located in the chamber which is a specially treated plastic material that responds to relative humidity changes. The indicator control has an accuracy of $\pm 5\%$ R.H.

The relative humidity will be adjusted by turning the front located knob, which in turn moves a red pointer to the scale setting desired. The humidity indicator control will be checked using a EL-TRONICS, INC. Remote reading humidity indicator-control model 301. A comparison read-out check will be used. A calibration adjustment screw is located on the front panel next to the control knob.

7.5.4.8 "Install Gas Cylinder" Pilot Light Check

During operation turn off the ETO cylinder supply pressure. When there is less than 20 psi indicated on the calibrated supply cylinder pressure gauge the "Install Gas Cylinder" pilot light should come on. Slowly open the supply valve on the gas cylinder, when the pressure gauge reads 20 psi or slightly above the pilot light will go out. If the above check out does not operate turn pressure limit switch adjustment screw (located below supply cylinder pressure gauge) clockwise, till the "Install Gas Cylinder" pilot light comes on when pressure is below 20 psi. Turn screw counterclockwise to turn pilot light off above 20 psi.

7.5.4.9 Temperature Controller Check

The temperature is set at the factory to maintain a temperature of $130^{\circ}\text{F} \pm 5^{\circ}\text{F}$ when set at 6-1/2. If adjustment has changed mark a tape and apply for new setting.

6.5.5 Two Door Steam Sterilizer (D-3) and (D-4)

6.5.5.1 The Castle Thermatic 60 Model _____ Sterilizer is designed to provide a complete sterilizing cycle. A variety of sterilizing cycles can be run manually or automatically on the thermatic 60.

6.5.5.2 Certification Requirements

6.5.5.2.1 The sterilizer door is equipped with a dual lock safety feature. An electrically controlled interlocking system and a bellows operated pressure lock will prevent opening of the door while a cycle is in progress.

6.5.5.2.2 Pressure gauges shall indicate the accurate jacket and chamber pressure of the sterilizer during operation to ± 1.5 p.s.i.

6.5.5.2.3 The pressure regulating valve will regulate the pressure in the sterilizing cycle. This valve shall be able to deliver any pressure up to the maximum available from the steam line.

6.5.5.2.4 Indicator recorder controller shall provide a permanent record of the sterilizing cycle.

6.5.5.2.5 The sterilizing timer will operate only when the temperature reaches the pointer setting on the recorder. The timer will reach zero only after continuous sterilization at or above the temperature of the pointer.

7.5.5 Two Door Steam Sterilizer D-3 and D-4.

7.5.5.1 Obtain a copy of the vendor's operating manual and become familiar with its contents before operating and conducting tests.

7.5.5.2 Pressure Gauge Check.

If the pointer shows a pressure or vacuum reading when there is positively no pressure in the chamber, unscrew the rim from the face of the gauge. Hold the pointer and turn the screw labeled "re-calibrate," opposite to which the pointer is to be moved. Gauges shall have been calibrated previous to the operational check and calibration stickers adhered to them. The above adjustment is simply a pointer re-set operation used when pointer has drifted.

7.5.5.3 Indicator Recorder Controller Check.

This instrument indicates, records and controls temperature during operation cycle. It is controlled by a sensing bulb in the chamber drain line.

7.5.5.3.1 Calibration of the one switch assembly on recorder.

This assembly controls the 90-minute timer. The switch will be calibrated by checking it audibly or by using a test light. If a test light is used, the switch can be checked by connecting across posts 17 and 2. The switch remains open until the indicating pointer reaches the temperature setting of the set pointer. It will then close the 90-minute timer.

To check adjustment audibly, position the set pointer at 250°F. Move the compensator located at the bottom of the controls. A click should be heard when the indicating pointer is at the exact setting of the set pointer. This indicates the circuit to the timer is closed. To adjust actuating point, reach in through the hole behind the chart and loosen the two top screws. Turn the slotted eccentric screw in either direction until the green indicating pointer agrees with the red set pointer. Tighten the two set screws after making adjustment.

7.5.5.3.2 Bellows to Indicator Check.

When the chamber pressure gauge reads 15 p.s.i., the indicating pointer should read 250°F. Allow steam regulator setting of 15 p.s.i. to stabilize. If the indicating pointer does not line up with the set pointer, adjust the bellows located inside recorder by turning the 1/4" hex adjustment nut, on the lower end of the bellows; "Out" to increase indicating temperature or "In" to decrease it.

7.5.5.3.3 Pen Calibration.

The pen writing point and the indicator pointer should agree throughout the range. To adjust the pen, loosen the adjustment screw and move the pen as desired. Re-tighten the screw.

7.5.5.4 Cycle Control Box.

7.5.5.4.1 Pressure switch PS-1 check. Pressure switch PS-1 closes at 1 p.s.i. chamber pressure. It energizes the lines to CAM switches S-12 and S-6 which moves the cycle from vent/dry or liquid cool to off.

If out of adjustment, it will be set audibly before making final adjustment with reference to pressure gauge. Turn adjustment screw counter-clockwise several turns. Then turn clockwise until a click is heard. Stop and turn slowly counter-clockwise until click is heard again. Continue to turn the adjustment screw 10 degrees beyond the point where the counter-clockwise click was heard. In the liquid cool phase of the liquid cycle, set pressure switch so that the cycle indicator will move from liquid cool to off when the pressure reaches 1 p.s.i. on the chamber pressure gauge.

7.5.5.4.2 Sterilizing Timer Check.

Check timer adjustment by running (2) three-minute cycles. No. 1 cycle will remove any play in the system. No. 2 the timer should run for three minutes (+1 -0).

7.5.5.4.3 Drying Timer

Check the timer adjustment by running (2) 10-minute cycle. The timer should run for 10 minutes (± 1 - 1).

7.5.5.5

Sterilock Interlocking Doors.

The interlocking door feature will permit opening of only one door at a time. Either door will be opened when the opposite door is closed and locked. To open either door when opposite door is locked, turn the door lock timer on the control panel to on and open the door.

After the cycle selections have been made, press the cycle start button on either the control or remote control panel to start cycle when both doors are locked.

7.5.5.5.1 Check adjustment of pressure lock by building up to 5 or 8 pounds steam pressure in the chamber.

Note: There shall be $(1/32 - 1/16)$ clearance between the ratchet teeth or the door cannot be opened at atmospheric pressure.
--

Vent the sterilizer slowly and try to turn the hand wheel to open the door as the pressure drops. Door shall remain locked until pressure drops to $1-1/2 - 3$ p.s.i. If door opens above 3 p.s.i. turn actuating rod clockwise and if below $1-1/2$ p.s.i., turn rod counter-clockwise. After completing adjustment, turn locknut tightly against the bottom ratchet.

7.5.5.5.2 Locking Bar Adjustment Check

All locking bars shall engage the head ring at about the same time that the hand wheel is turned clockwise to seal the door. If not properly adjusted, steam will escape from the door gasket that is not being compressed. If steam escapes, keep door closed and locked, then turn hand wheel clockwise and check the locking bars until they begin to tighten. Remove shims under bars that tighten too soon and add to those that are loose.

7.5.5.6 Temperature, Vacuum and Pressure Recorder.

This instrument indicates and records, but does not control. During operation of sterilizer, observe recorder operation and compare chart readings with pressure gauges and temperature indicator-controller. Adjustments screws for pens are located on the front face of the recorder and are color coded to agree with pens. Accuracy is one division on chart paper.

6.5.6 Two Ton Electric Hoist

(BUDGET - Portable Electric)

6.5.6.1 The "BUDGET" portable electric hoist is a precision built chain-type hoist. The two at the SADL Facility are Lug Suspended and both hoist and Lug Suspension bracket are rated at 4000 pound capacity. The hoists have been modified by the addition of a sheet-metal cover and chain receptacle and the addition of a neoprene accordion type dust cover. The neoprene cover is further encased in nylon and polyethylene tubing in order to reduce the possibility of physical or biological contamination from the hoist migrating to the spacecraft during assembly operations.

6.5.6.2 The hoist will be certified for use in the SADL Facility if the following parameters are found to be within the range of manufacturers' specifications and current SADL requirements.

6.5.6.3 Certification Requirements

6.5.6.3.1 Chain links shall be checked for elongation - maximum allowable length of 11 pitches is 9.55 inches, (check should be in at least 3 distinct points with at least one (1) point checked in

the portion of the chain which passes through the hoist during normal operation).

- 6.5.6.3.2 Visually inspect chain lower block assembly and Lug Suspension for visible distortion, nicked, gouged, or twisted links -- if damage is found, replace entire chain or damaged link.
- 6.5.6.3.3 Visually inspect motor frame, end cover and gear box - oil level. Replace any damaged components including loser hook assembly. Maximum lower hook opening is 1 3/8 inches. Add oil if required, per maintenance instructions.
- 6.5.6.3.4 Hoisting speed shall be checked for average velocity over a lift distance of at least 10 ft. Velocity shall be 4 ± 0.4 fpm at all times for either raising or lowering with empty hook.
- 6.5.6.3.5 Hoist motor brake shall function automatically when empty hook is moved to highest position.
- 6.5.6.3.6 The hoist shall be proof-tested at rated capacity of 4,000 pounds with the unit installed at the point of useage (including handling devices).
- Note: Proof testing shall be accomplished with the chain extended to maximum length

as limited by height of hoist above
the floor and with the neoprene cover
removed so that the chain is exposed
for inspection purposes.

The hoist under full proof load shall be capable
of being stopped at any point and holding the
load without visible slippage for at least 30
seconds when either raising or lowering the
load.

6.5.6.3.6 Push button control on both the wall-mounted
push button and the pendant-mounted push button
shall be in agreement relative to raising and
lowering of the load.

7.5.6 Two Ton Electric Hoist - Certification Test Plan
(BUDGET - Portable Electric)

7.5.6.1 Test Equipment and Test Requirements

The following listed equipment, or an equipment item which is acceptable to Quality Assurance shall be required in establishing compliance with section 6.5.6.3.

7.5.6.1.1 Stop watch or electric timer accurate to ± 0.2 seconds over a $2\frac{1}{2}$ minute cycle.

7.5.6.1.2 Inside vernier caliper with 10 inch range - accuracy ± 0.015 in.

7.5.6.2 Preparation for Testing

7.5.6.2.1 Tape 3 or more layers of heavy brown wrapping paper in place directly under hoist to protect perforated floor grills.

7.5.6.2.2 Remove neoprene and/or nylon protective covering so that load chain is fully exposed.

7.5.6.3 Testing Sequence and Operations

7.5.6.3.1 Check at least three (3) points for elongation against inside vernier caliper over length of 11 pitches.

7.5.6.3.2 Conduct visual inspection of:

- a. chain
- b. lower block assembly
- c. lug suspension

Obtain Q.A. signature prior to proceeding.

7.5.6.3.3 Conduct visual inspection of:

- a. motor frame
- b. end cover
- c. gear box - oil level

Obtain Q. A. signature prior to proceeding

7.5.6.3.4 Check lift rate over a measured distance of at least 10 ft. Time shall be checked against stopwatch or timer for both raise and lower rates of empty hoist.

7.5.6.3.5 Push raise button and hold while chain hoist is raised to highest position. Motor shall automatically shut-off before hook comes in contact with hoist housing.

7.5.6.3.6 The hoist shall be proof loaded by picking up

a gross weight of $4,000 \pm 80^0$ pounds from floor level. Hoist shall hold maximum rated load without slipping for a period of 30 seconds.

7.5.6.3.7 Check push button controls for continuity in color codes between raise and lower buttons (Pendant vs. Wall Mounts).

7.5.6.4 Data Review

Upon completion of all tests outlined in section 7.5.6.3 the results shall be reviewed for compliance with section 6.5.6.3.

6.5.7 Two Door Dry Heat Sterilizer

6.5.7.1 The two door dry heat sterilizer is a wall-mounted unit manufactured by the Blue M. Electric Co. It is useable over the range of temperatures from ambient to 343°C (650°F). It will hold any pre-set temperature to $\pm 3^{\circ}\text{C}$. There is no cooling capacity.

6.5.7.2 The unit must meet the requirements of the vendor specification.

6.5.7.2.1 The internal dimensions shall be at least 19 in. by 19 in. by 25 in.

6.5.7.2.2 The temperature within the unit shall be controlled to $\pm 3^{\circ}\text{C}$ over a temperature range of ambient to 343°C .

6.5.7.2.3 An alarm system shall operate if the temperature exceeds that set in the over-temperature protection.

7.5.7 Two Door Dry Heat Sterilizer

7.5.7.1 The two door dry heat sterilizer shall be installed by the general contractor and connected electrically into a permanent installation.

7.5.7.2 Obtain a copy of the vendor's specification and become familiar with its contents. Do not attempt to start the test until the principle of operation is thoroughly understood.

7.5.7.2.1 Measure and record on the data sheet the useable space in the chamber.

7.5.7.2.2 Set up a remote indicating thermocouple in the vicinity of the thermocouple installed permanently in the oven.

7.5.7.2.2.1 Set the memory ring dial at 125°C with the vernier type index at 0. Set the over temperature protection dial at 145°C with the vernier type index at 0.

7.5.7.2.3 Turn on the oven and allow the temperature to stabilize.

Note: When the oven is turned on, the volt meter will read about 208v. As the temperature in the chamber approaches that set into the dial the voltage will begin to fall off. When the temperature has stabilized, the voltage will read about 10v.

When the temperature is stabilized, observe and record the dial indicator, the indication on the remote thermometer and the built-in thermometer. If these readings are more than ±3°C apart, adjust the built-in thermometer to agree with the remote indicating

thermometer. Then adjust the memory ring dial so that one of the vernier numbers lines up with the required 125°C and allow the oven temperature to re-stabilize at this new temperature. If the thermometer and dial readings are now within 3°C observe the number on the vernier type indicator that is lined up with the 125°C . Using a permanent marking device, record this number on the white area next to the vernier in line with the number.

7.5.7.2.4 Increase the setting on the memory ring dial approaching the reading on the over temperature protection dial. Observe that the alarm functions.

7.5.7.2.5 Reset the memory ring dial at 175°C with the vernier type setting at 0.

Reset the over temperature protection dial to 195°C with the vernier type indicator at 0.

Allow the oven temperature to stabilize at the pre-set temperature and observe the reading on the built-in thermometer and the remote indicating thermometer. All three readings should be within $\pm 3^{\circ}\text{C}$ of dial setting. If the thermometers and dial setting disagree, reset the dial until the thermometers read 175°C . Note the vernier type number in line with 175°C and write the number in the white space adjacent to the number which brings the temperature of the oven within tolerance.

- 7.5.7.2.6 Turn off the oven and allow it to cool (about 24 hours). Re-set both the memory dial and the oven protection dial to the final readings obtained in 7.5.7.2.1. Observe that the oven stabilized at $124^{\circ}\text{C} \pm 3^{\circ}\text{C}$ and holds that temperature and tolerance for 24 hours.
- 7.5.7.2.7 Reset the oven to the final setting obtained at 175°C and allow the oven to stabilize. Observe that the remote, and built-in thermometers read the preset temperature with $\pm 3^{\circ}\text{C}$. Observe the temperature for 3 hours and record any deviations.
- 7.5.7.2.8 If the two thermometers do not agree, the built-in thermometer can be re-set. If it is necessary to re-set the thermometer it shall be required that the test be run again at each of the two temperature positions.
- 7.5.7.2.9 Set the memory ring dial at 300°C , with the vernier type indicator at 0. Set the oven temperature protection dial at 340°C with the vernier indicator at 0. Allow the temperature to stabilize. Adjust the memory dial until the built-in thermometer reads 300°C .
Write on the white ring with the number corresponding to the 300°C position on the vernier type dial. Record the remote thermometer reading. It is not necessary to re-adjust the built-in thermometer to agree with the remote thermometer.

6.5.8 Glass Dryer

6.5.8.1 The glass dryer is a floor mounted unit manufactured by the Blue M. Electric Co. It is useable over the range of temperatures from ambient to 343°C (650°F). It will hold any pre-set temperature to $\pm 3^{\circ}\text{C}$. There is no cooling capacity.

6.5.8.2 The unit must meet the requirements of the vendor specification.

6.5.8.2.1 The internal dimensions shall be at least 38" wide by 20" deep by 25" high.

6.5.8.2.2 The temperature within the unit shall be controlled to $\pm 3^{\circ}\text{C}$ over a temperature range of ambient to 343°C .

6.5.8.2.3 An alarm system shall operate if the temperature exceeds that set in the over-temperature protection.

7.5.8 Glass Dryer

7.5.8.1 The glass dryer shall be installed by the general contractor and connected electrically into a permanent installation.

7.5.8.2 Obtain a copy of the vendor's specification and become familiar with its contents. Do not attempt to start the test until the principle of operation is thoroughly understood.

7.5.8.2.1 Measure and record on the data sheet the useable space in the chamber.

7.5.8.2.2 Set up a remote indicating thermocouple in the vicinity of the thermocouple installed permanently in the oven.

7.5.8.2.2.1 Set the memory ring dial at 80°C with the vernier type index at 0. Set the over temperature protection dial at 100°C with the vernier type index at 0.

7.5.8.2.3 Turn on the oven and allow the temperature to stabilize.

Note: When the oven is turned on, the meter will read full deflection. As the temperature in the chamber approaches that set into the dial the needle will begin to fall off. When the temperature has stabilized, the needle will read about 25%.

When the temperature is stabilized, observe and record the dial indicator, the indication on the remote thermometer and the built-in thermometer. If these readings are more than $\pm 3^{\circ}\text{C}$ apart, adjust the built-in thermometer to agree with the remote indicating thermometer. Then adjust the memory ring dial so that one of the vernier

type indicator that is lined up with the 80°C .

Using a permanent marking device, record this number on the white area next to the vernier in line with the number.

7.5.8.2.4 Increase the setting on the memory ring dial approaching the reading on the over temperature protection dial. Observe that the alarm functions.

7.5.8.2.5 Reset the memory ring dial at 175°C with the vernier type setting at 0.

Reset the over temperature protection dial to 195°C with the vernier type indicator at 0. Allow the oven temperature to stabilize at the pre-set temperature and observe the reading on the built-in thermometer and the remote indicating thermometer.

All three readings should be within $\pm 3^{\circ}\text{C}$ of dial setting.

If the thermometer and dial setting disagree, reset the dial until the thermometers read 175°C . Note the vernier type number in line with 175°C and write the number in the white space adjacent to the number which brings the temperature of the oven within tolerance.

7.5.8.2.6 Turn off the oven and allow it to cool (about 24 hours).

Re-set both the memory dial and the oven protection dial to the final readings obtained in 7.5.8.2.1.

Observe that the oven stabilizes at $80^{\circ}\text{C} \pm 3^{\circ}\text{C}$ and holds that temperature and tolerance for 24 hours.

- 7.5.8.2.7 Reset the oven to the final setting obtained at 175°C and allow the oven to stabilize. Observe that the remote, and built-in thermometers read the pre-set temperature with $\pm 3^{\circ}\text{C}$. Observe the temperature for 3 hours and record any deviations.
- 7.5.8.2.8 If the two thermometers do not agree, the built-in thermometer can be re-set. If it is necessary to re-set the thermometer it shall be required that the test be run again at each of the two temperature positions.
- 7.5.8.2.9 Set the memory ring dial at 300°C, with the vernier type indicator at 0. Set the oven temperature protection dial at 340°C with the vernier indicator at 0. Allow the temperature to stabilize. Adjust the memory dial until the built-in thermometer reads 300°C.
- Write on the white ring with the number corresponding to the 300°C position on the vernier type dial.
- Record the remote thermometer reading. It is not necessary to re-adjust the built-in thermometer to agree with the remote thermometer.

6.5.9 High Speed Refrigerated Centrifuge

6.5.9.1 The Lourdes Model A-2 "BETA-FUGE" is a portable, automatic, refrigerated console type centrifuge with fourteen interchangeable rotors offering acceleration forces up to a maximum of 41,300G on a 400 ml volume and with a maximum handling capacity of 3,000 ml. The centrifuge in the SADL facility is equipped only with a model 9RA rotor offering 41,300G and a volume capacity of 400 ml.

6.5.9.2 Acceptability of the unit for use in the SADL program will be established upon certification that the unit controls and instrumentation are accurate within manufacturer's specifications and that the performance parameters encompass the scope of SADL requirements.

6.5.9.3 Certification Requirements.

NOTE: ALL TESTS SHALL BE CONDUCTED IN ACCORDANCE WITH THE MANUFACTURER'S "OPERATION AND INSTALLATION MANUAL" DATED 1966, AND WITH AN EMPTY TYPE 9RA SOLID ANGLE ROTOR INSTALLED.

6.5.9.3.1 Temperature Control and Range Certification shall be accomplished by operating the refrigeration system and controls over the entire control range (-20°C to $+40^{\circ}\text{C}$). Upon starting the centrifuge the time required for precooling the system, from room ambient (24°C) to -20°C , shall be continuously monitored. The system shall be capable of attaining 0°C within 20 minutes and -20°C within 40 minutes from startup time. Temperature control and indicators shall be checked at a minimum of 7 settings in equal intervals, including both end-points over the entire range.

All readings of both the Temperature Control Indicator and Temperature Indicator shall read within $\pm 1^{\circ}\text{C}$ of the actual temperature at the sensing bulb. Readings shall be checked on both an increasing and a decreasing scale of values.

6.5.9.3.2 Automatic Timer certification shall be accomplished by checking the timer over the entire range. A minimum of five settings at equal intervals shall be checked including the full scale range. The accuracy at all points checked shall be within ± 2 minutes and the repeatability of specific settings shall be within $\pm 1\%$ of the time interval measured.

6.5.9.3.3 Speed Indicator certification shall be conducted simultaneously with Speed Control and Range certification which follows in paragraph 6.5.9.3.4. Tachometer readings shall be taken at a minimum of 7 points, including both end-points, across the Tachometer scale. All readings shall be correct within $\pm 1\%$ of the actual rotor rpm on both an increasing and decreasing scale.

6.5.9.3.4 Speed Control and Range certifications shall be accomplished upon verification that the variable speed selector is accurate within $\pm 3\%$ of the indicated reading over the full scale range (0-18,000 rpm). A minimum of 7 scale settings shall be checked, including both end-points, on both an increasing and a decreasing scale. Repeatability of selector settings shall be within $\pm 1\%$ of the actual rotor rpm. A minimum of two minutes shall be allowed between readings to insure that the angular acceleration is zero. Upon completion of selector certification the equipment shall be shut down and restarted. The equipment shall be capable of attaining maximum rpm (18,000 rpm) within a maximum time of 105 seconds. Upon turning off the master switch, the equipment shall come to a full stop within a maximum time of 265 seconds.

7.5.9 High Speed Refrigerated Centrifuge - Certification Test Plan

7.5.9.1 Test Equipment & Test Requirements

The following listed equipment, or an equivalent item acceptable to Quality Assurance shall be required in establishing compliance with Section 6.5.9.3.

7.5.9.1.1 Strobatac, GE or equivalent, with built-in in calibration check against 60 cycle frequency.

7.5.9.1.2 Stopwatch or Electric Timer, minimum range 2 hour, minimum accuracy ± 15 sec.

7.5.9.1.3 Precision Temperature Potentiometer or millivolt potentiometer with ice point reference junction.

NOTE: COMBINED ACCURACY OF POTENTIOMETER, THERMOCOUPLES AND CALIBRATED LEADS SHALL NOT EXCEED $\pm 0.5^{\circ}\text{C}$.

7.5.9.1.4 Industrial type volt-ammeter, e.g. Simpson, Model 260, accuracy $\pm 3\%$ of full scale reading.

7.5.9.2 Preparation For Testing

The centrifuge shall be checked for visible damage prior to testing. If unit has not previously been tested or has been shipped to new location during normal operation it is imperative that the following be verified:

7.5.9.2.1 Power requirements

208v, 60 cycle, 3 phase (check nameplate voltage vs incoming line voltage-max. voltage fluctuation allowable is $\pm 10\%$.)

- 7.5.9.2.2 Remove lower section of the back to remove the wooden board which immobilizes the refrigeration unit (board is visible on the left side of unit).
- 7.5.9.2.3 Rotor Selection and Seating.
An empty model 9RA solid rotor shall be used for testing purposes. Place the rotor directly on to the drive shaft and engage cross-pin per manufacturer's instructions.
- 7.5.9.2.4 Set up timer or stopwatch such that timer can be actuated simultaneously with the master switches.
- 7.5.9.2.5 Set up strobatac with adequate extension cord to allow proper viewing of rotor.
- 7.5.9.2.6 Set up temperature potentiometer and install thermocouple sensing elements as required to monitor the following temperatures.
- 7.5.9.6.1 Room ambient
- 7.5.9.6.2 Equipment operating temperature
(Thermocouple shall be installed as close as is feasible to the internal sensing element.)
- 7.5.9.3 Testing sequence and operations
- 7.5.9.3.1 Temperature control and range certification.
Proceed with testing as follows;

7.5.9.3.1.1 Record the following data:

7.5.9.3.1.1.1 Room ambient temperature

7.5.9.3.1.1.2 Equipment temperature (standard)

7.5.9.3.1.1.3 Equipment temperature indicator
reading.

7.5.9.3.1.2 Set Temperature Control Indicator at -20°C .

7.5.9.3.1.3 Throw both circuit breakers (rear panel) to "ON"
position.

7.5.9.3.1.4 Simultaneously activate the timer, (standard),
referred to in paragraph 7.5.9.3.4. and throw both
master switches (refrigeration and centrifugation)
to "ON" position.

7.5.9.3.1.5 Set speed-set potentiometer to 5,000 RPM.

7.5.9.3.1.6 After 20 minutes of operation, (from startup),
record the following:

7.5.9.3.1.6.1 Room ambient temperature

7.5.9.3.1.6.2 Equipment temperature (standard)

7.5.9.3.1.6.3 Equipment temperature indicator
reading.

7.5.9.3.1.7 After 40 minutes of operation, (from startup),
record the following:

7.5.9.3.1.7.1 Room ambient temperature.

7.5.9.3.1.7.2 Equipment temperature (standard)

7.5.9.3.1.7.3 Equipment indicator reading.

7.5.9.3.1.8 The temperature shall be allowed to stabilize at the
 -20°C setting of the temperature control indicator
before proceeding. Stable temperatures shall be
assumed when the equipment temperature (standard)
has not changed for a period of 5 minutes.

The stabilization procedure shall be followed at all subsequent temperature settings in 10° increments over the entire temperature control indicator range (include both end-points). At each temperature setting the following data shall be recorded on both an increasing and a decreasing scale.

- 7.5.9.3.1.8.1 Room ambient temperature.
- 7.5.9.3.1.8.2 Equipment temperature (standard).
- 7.5.9.3.1.8.3 Equipment temperature indicator reading.
- 7.5.9.3.1.8.4 Temperature deviations at intermediate settings shall be calculated to determine the repeatability of specific settings.

Upon completion of this section the temperature control shall be set at zero (0°C) degrees and allowed to stabilize for Speed Control and Range Certification, as outlined in Paragraph 7.5.9.3.3 & 4.

7.5.9.3.2 Automatic Timer Certification

- 7.5.9.3.2.1 The time interval shall be checked against the Timer at 20-minute increments over the entire range of the Automatic Timer. The checking of the Timer shall be conducted while temperature and/or Speed Control testing is in progress. A minimum of two (2) comparisons shall be made and recorded at each setting. Data recorded shall include

- 7.5.9.3.2.1.1 Automatic Timer setting

- 7.5.9.3.2.1.2 Actual time interval (stopwatch or timer).

7.5.9.3.3 Speed Indicator Certification

Tachometer certification testing shall be conducted jointly with Speed Control and Range Certification as outlined in the following paragraph, 7.5.9.3.5.

7.5.9.3.4 Speed Control and Range Certification

7.5.9.3.4.1 A total of seven (7) points, including both end points, shall be checked in 3000 RPM increments across the range of the Speed Control Selector. All readings shall be taken with the temperature control stable at zero (0°C) degrees and minimum of two readings shall be taken at all intermediate points on both an increasing and a decreasing scale. A minimum of two minutes shall be allowed between readings to insure that the angular acceleration is zero. The following data shall be recorded at each setting.

7.5.9.3.4.1.1 Speed Control Selector setting.

7.5.9.3.4.1.2 Rotor rpm (strobotac reading).

7.5.9.3.4.1.3 Tachometer reading.

7.5.9.3.4.1.4 Rotor rpm deviations shall be calculated at intermediate settings to determine repeatability.

Upon completion of the preceding readings both master switches shall be turned to the "OFF" position and the equipment allowed to come to a complete stop.

7.5.9.3.4.2 Set the Speed Control selector at the maximum (18,000) rpm.

7.5.9.3.4.3 Activate the timer (standard) and throw both master switches to the "ON" position simultaneously.

7.5.9.3.4.4 Observe the Tachometer and stop timer upon attainment of the maximum rpm. Record the following:

7.5.9.3.4.4.1 Final rpm attained.

7.5.9.3.4.4.2 Time (seconds) required to attain maximum rpm.

7.5.9.3.4.5 Activate the timer and throw both master switches to the "OFF" position simultaneously.

7.5.9.3.4.6 Observe the rotor and stop timer when the rotor comes to a complete stop. Record the following:

7.5.9.3.4.6.1 Initial rpm.

7.5.9.3.4.6.2 Time (seconds) to come to a complete stop.

7.5.9.4 Data Review

Upon completion of all tests outlined in Section 7.5.9.3 the results shall be reviewed for compliance with Section 6.5.9.3 requirements.

6.5.10 Incubator, Humidity Controlled

6.5.10.1 The Hotpack Model 1232 incubator is a cabinet type, heated-humidified chamber with circulating blower and exhaust vent. The temperature is controllable over the range of $30^{\circ}\text{C} - 60^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. and the humidity is controllable within the range of $10\% - 98\% \text{ RH} \pm 5\% \text{ RH}$, when operated within a controlled ambient of 22°C and $42\% \text{ RH}$, depending upon the dry bulb temperature maintained within the chamber.

6.5.10.2 Acceptability of the unit for use in the SADL program will be established upon certification that the unit controls and indicators are accurate within the manufacturer's specifications and that the performance parameters encompass the scope of SADL requirements.

6.5.10.3 Certification Requirements.

NOTE: ALL TESTS SHALL BE CONDUCTED IN ACCORDANCE WITH THE MANUFACTURER'S OPERATING INSTRUCTIONS AS OUTLINED IN HOTPACK INSTRUCTION J-253, FORM 22611.

6.5.10.3.1 Temperature control and range certifications shall be accomplished by operating the unit over the temperature range of $30^{\circ}\text{C} - 60^{\circ}\text{C}$. Only three (3) points shall be checked to determine if range capacity and accuracy have been satisfied. The check points shall be at 32°C , 37°C & 55°C . Actual temperature after stabilization shall not vary more than $\pm 0.5^{\circ}\text{C}$ of both the dial indicator setting and the internal thermometer reading when sensed at the thermometer sensing element.

6.5.10.3.2 Limitstat control switch shall be checked by rotating the control knob through the thermostat setting, after control has been attained, to verify that the circuit to the heater is broken when temperature exceeds the limitstat setting.

6.5.10.3.3 Humidity control and indicators shall be certified for control at a wet bulb setting of 23.6°C in conjunction with a dry bulb setting of 32°C only. Range and control shall be checked and recorded at a wet bulb setting of 32.2°C in conjunction with dry bulb setting of 37°C and 55°C , respectively, however, a relative humidity control point which indicates a wet bulb reading other than 32.2°C shall be acceptable on a conditional basis.

*6.5.10.3.4 The hygrometer indicator shall be checked by comparison against the actual humidity conditions measured within the incubator at the three conditions spelled out in paragraph 6.5.10.3.3. After stable conditions have been attained, the indicator shall register within $\pm 5\%$ of the actual relative humidity measured.

*NOTE: The $\pm 5\%$ requirement on the hygrometer indicator is an arbitrary value assigned in this procedure and is not a specified performance parameter by the equipment supplier.

7.5.10 Incubator, Humidity Controlled - Certification Test Plan

7.5.10.1 Test Equipment & Test Requirements

The following listed equipment, or an equivalent item, which is acceptable to Quality Assurance, shall be required in establishing compliance with Section 6. 5.10.3.

7.5.10.1.1 Precision Temperature Potentiometer or millivolt potentiometer with ice-point reference junction (e.g. L. & N. Portable Temperature Potentiometer).

NOTE: COMBINED ACCURACY OF POTENTIOMETER, THERMOCOUPLES AND CALIBRATED LEADS SHALL NOT EXCEED $\pm 0.25^{\circ}\text{C}$. (USE HG-IN-GLASS IF PORTABLE THERMOCOUPLE INSTRUMENTATION WITH REQUIRED ACCURACY IS NOT AVAILABLE.)

7.5.10.1.2 Portable Humidity Indicator, minimum accuracy of $\pm 2.5\%$ RH, (e.g. Honeywell, Model 611A).

7.5.10.1.3 Industrial volt-ammeter (e.g. Simpson, Model 260, $\pm 3\%$ of full scale).

7.5.10.2 Preparation for Testing

7.5.10.2.1 Place humidity sensing element in vicinity of printed circuit board sensing element.

7.5.10.2.2 Place temperature sensing element on top shelf of incubator. (In full view if Hg-in-Glass is used and in calibrated position).

7.5.10.2.3 Sling psychrometer shall be used for obtaining ambient temperature and humidity conditions in laboratory (Ambient conditions shall be maintained at $\text{DB}=70^{\circ}$, $+7$, -3°F and $\text{R H.} = 45 \pm 5\%$ throughout testing of the incubator).

7.5.10.3 Test Sequence and Operations

7.5.10.3.1 Temperature Control and range certification tests shall be conducted as follows:

7.5.10.3.1.1 Place humidity switch on "LOW" Setting.

7.5.10.3.1.2 Set humidity thermostat (wet bulb) at 23.6°C.

7.5.10.3.1.3 Set exhaust valve at full open (adjust during testing if required in order to raise humidity to reach control points).

7.5.10.3.1.4 Turn limitstat potentiometer to high setting.

7.5.10.3.1.5 Prior to starting incubators record the following:

7.5.10.3.1.5.1 Ambient dry-bulb temperature.

7.5.10.3.1.5.2 Ambient wet bulb temperature.

7.5.10.3.1.5.3 Ambient relative humidity shall be calculated from wet bulb depression or taken from standard psychromatic chart.

7.5.10.3.1.6 Throw master switch to "ON" position.

7.5.10.3.1.7 Set incubator temperature thermostat at 32°C

7.5.10.3.1.8 While incubator is coming to control temperature the internal calibration of the equipment hygrometer shall be checked for calibration by switching hygrometer switch to "CHECK" position and adjusting calibration screw if required.

7.5.10.3.1.9 Turn hygrometer switch to "ON" position for balance of testing.

7.5.10.3.1.10 When stable temperatures have been attained as evidenced by no change in instrumentation over a period of at least 5 minutes the following data shall be recorded:

- 7.5.10.3.1.10.1 Ambient temperature, DB
- 7.5.10.3.1.10.2 Ambient temperature, WB
- 7.5.10.3.1.10.3 Actual incubator temperature,
DB (standard)
- 7.5.10.3.1.10.4 Actual incubator R.H. (standard).
- 7.5.10.3.1.10.5 Incubator hygrometer reading.
- 7.5.10.3.1.10.6 Incubator temperature, DB
(equipment thermometer).
- 7.5.10.3.1.10.7 Calculate ambient RH

7.5.10.3.1.11 Repeat steps 7.5.10.3.1.7 thru 10 for incubator temperature thermostat settings of 37°C and 55°C with a constant incubator humidity thermostat setting of 32.2°C.

NOTE: IF ADJUSTMENT TO THERMOSTAT DIAL SETTINGS ARE REQUIRED THEY SHALL BE ADJUSTED SUCH THAT THE FOLLOWING POINTS ARE CORRECT:

DRY BULB = 32°C

WET BULB = 23.6°C

7.5.10.3.2 Limitstat certification shall be established while the incubator is controlling at a set condition. Proceed as follows:

7.5.10.3.2.1 Turn the limitstat to a setting below the control point.

7.5.10.3.2.2 Check for zero (0) voltage across terminals 17 and 14 on back of control panel with industrial volt-ammeter (if potential is registered switch is defective).

7.5.10.3.3 Humidity control and indicator certification testing shall be conducted jointly with temperature control and range certification as outlined in section 7.5.10.3.1

7.5.10.3.4 Hygrometer indicator certification testing shall be conducted jointly with temperature control and range certification as outlined in section 7.5.10.3.1.

7.5.10.4 Data Review

Upon completion of all tests outlined in section 7.5.10.3 the results shall be reviewed for compliance with section 6.5.10.3 requirements.

6.5.11 Laminar Flow Bench
Baker Edgegard Hood

6.5.11.1 The "BAKER EDGEGARD HOOD," Model EG 4220, is a self contained laminar flow, work bench designed to provide clean, filtered, laminar flow air meeting U.S.A.F. T.O. 00-25-203 and Federal Standard 209.

6.5.11.2 The Laminar Flow Bench will be certified upon verification of the level of illumination air velocity and effectiveness of the absolute filter.

6.5.11.3 Certification Requirements

6.5.11.3.1 Illumination of the lighting level when measured at the work surface shall be no less than 200 foot candles.

6.5.11.3.2 The air velocity as measured across the entire face of the absolute filter shall be $*100 \pm 10$ fpm.

6.5.11.3.3 The "HEPA" filter shall be leak checked by the performance of a standard "smoke" or "DOP" test. Any leaks detected by a photometer reading of 0.01% of the upstream smoke concentration shall be sealed off prior to certification.

NOTE: Upper limit not specified by manufacturer and has been assigned on basis of Federal Standard 209a requirements.

7.5.11. Laminar Flow Bench - Certification Test Plan
(Baker Edgegard Hood)

7.5.11.1 Test Equipment & Test Requirements

The following listed equipment, or an equipment item which is acceptable to Quality Assurance, shall be required in establishing compliance with Section 6.5.11.3.

7.5.11.1.1 Weston Light Meter, Industrial Type

7.5.11.1.2 Recording Anemometer, Gelman-Wallac
Model GGA2C,

7.5.11.1.3 Smoke Generator and Atomizing Nozzle,
Royco Model WA, 18 cfm maximum capacity
0.3 Micron and smaller particle size.

7.5.11.1.4 Photometer, Sinclair Phoenix
Particulate Counter, Model U 2000.

7.5.11.2 Preparation For Testing.

The laminar flow bench shall be checked for visible damage to the bench or components prior to the initiation of the following tests which will be required for certification. Any defective components or visible damage shall be noted on the test report prior to commencing the tests. A complete vacuuming and cleaning of the unit shall have been conducted prior to testing.

The power required for operation is 110 volt, 60 cycle, single phase. The power source shall be properly grounded and provided by standard 3-prong receptacle to receive the unit service cord (unit may be permanently wired if physical location is permanent).

7.5.11.2.1 Turn both light switch and blower switch to "ON" position.

7.5.11.2.2 Check to ascertain that all lights are on and that the blower is delivering air across the work station.

7.5.11.2.3 Allow unit to run for a minimum of 10 minutes and then conduct the certification tests as outlined below.

7.5.11.3 Testing Sequence and Operations

7.5.11.3.1 Illumination Test

7.5.11.3.1.1 The lighting level shall be checked with the light meter laying on the work bench surface.

7.5.11.3.1.2 The light meter shall be moved such that the entire area is scanned with a minimum of six (6) readings being recorded.

7.5.11.3.2 Velocity Test

7.5.11.3.2.1 The velometer and probe shall be set up and checked in accordance with manufacturer's instructions.

7.5.11.3.2.2 Velometer readings shall be recorded at a minimum of eight points, on a grid, across the face of the absolute filter.

7.5.11.3.2.3 In scanning the entire face of the filter any indication of a reading outside the specified tolerances shall be checked and recorded in addition to the selected grid points.

7.5.11.3.3 Filter Leak Test

7.5.11.3.3.1 The portable smoke generator shall be started and the required smoke concentration, for 100% deflection of the aerosol photometer, introduced to the plenum upstream of the Absolute filter. (28.8 scpm of undiluted concentration-minimum allowable concentration).

7.5.11.3.3.2 The entire downstream surface area of the absolute filter and all seals shall be scanned with the aerosol photometer.

7.5.11.3.3.3 Any photometer readings in excess of the maximum allowable readings shall result in voiding of the entire leak test until specific leaks are sealed.

7.5.11.3.3.4 When all photometer readings are within the allowable leakage rate the maximum reading notes shall be recorded.

7.5.9.5 Data Review

Upon completion of all tests outlined in Section 7.5.11.3 the results shall be reviewed for compliance with Section 6.5.11.3 requirements.

6.5.12 Laboratory Glassware Washer

6.5.12.1 The Heinicke Model HW5000-E-Laboratory Glassware Washer with patented Heinicke jet system is a completely automatic washer with distilled water rinse designed to meet or exceed the requirements of the Veterans Administration Specification SS-S-300, dated 1 May 1964 and the US National Institute of Health Specifications dated March 1962 (revised October 1963).

6.5.12.2 Acceptability of the unit for use in the SADL program will be established upon certification that the unit dial thermometer is correct within manufacturer's tolerances and upon satisfactory performance of a complete wash and rinse cycle.

6.5.12.3 Certification Requirements

NOTE: ALL OPERATIONAL TESTS SHALL BE CONDUCTED IN ACCORDANCE WITH THE MANUFACTURER'S "DIRECTIONS FOR USE" MANUAL, SECTIONS COVERING INSTALLATION AND OPERATION, PAGES 2 THROUGH 4.

6.5.12.3.1 Temperature Indicator shall be checked for accuracy at a minimum of five (5) points, over the range of 100-220°F.

NOTE: All points checked shall be accurate within $\pm 6.6^{\circ}\text{F}$. Readings shall be checked on an increasing scale only and shall be checked at least within 5° of the dial end points (100° & 220°F.)

6.5.12.3.2 Operational Testing shall be accomplished by running one complete wash and rinse cycle with all controls functioning in accordance with the manufacturer's operational instructions. Operational Testing shall be performed after temperature indicator calibration.

7.5.12 Laboratory Glassware Washer - Certification Test Plan

7.5.12.1 Test Equipment and Requirements

7.5.12.1.1 Portable Temperature Potentiometer or Hg-in-glass thermometers.

NOTE: Combined accuracy of potentiometer, immersible thermocouple and leads shall not exceed $\pm 1.5^{\circ}\text{F}$. (Note: If Hg-in-glass type standards are used they shall be at least $\pm 0.5^{\circ}\text{F}$ with traceability to NBS.

7.5.12.1.2 Industrial type voltammeter, e.g. Simpson Model 260, accuracy $\pm 3\%$ of full scale reading.

7.5.12.1.3 Laboratory type constant temperature bath with heater, variable reostat and stirrer.

7.5.12.2 Preparation for Testing

7.5.12.2.1 Set up temperature potentiometer or Hg-in-glass standards as required to monitor the following temperatures.

7.5.12.2.1.1 Room Ambient

7.5.12.2.1.2 Constant temperature bath.

7.5.12.2.2 Power Requirements

The glassware washer shall be checked for visible damage prior to testing and the electrical characteristics of power supplied verified as follows:

NOTE: MAX VOLTAGE FLUCTUATION ALLOWABLE IS $\pm 10\%$.

7.5.12.2.2.1 Heating elements (12,000w)-208/60/3

7.5.12.2.2.2 Wash Pump (1-1/2 or 2 HP)-208/60/3

7.5.12.2.2.3 Rinse Pump (1/3 HP)-110/60/1

7.5.12.2.2.4 Drive Motor (1/15 HP)-110/60-1

7.5.12.2.2.5 Proceed with test sequence and operations.

7.5.12.3 Test Sequence and Operations

7.5.12.3.1 Temperature Indicator Calibration.

7.5.12.3.1.1 Remove dial temperature indicator and calibrate at five (5) points on increasing scale per Paragraph 6.5.12.3.1 by comparison to standard in constant temperature bath. (Note: Correct readings for ambient error per standard emergent stem correction, if Hg-in-glass is used for standard).

7.5.12.3.1.2 Recheck one (1) point only in the range of 100-105°F to assure repeatability within indicator accuracy.

7.5.12.3.1.3 Replace calibrated dial temperature indicator and proceed with operational testing of the unit.

7.5.12.3.2 Operational Test.

Refer to paneled timer.

7.5.12.3.2.1 Turn Power Switch to "ON" position.

7.5.12.3.2.2 Turn Auto-Manual Switch to "MANUAL" position.

7.5.12.3.2.3 Turn lower rinse switch (center switch) to "ON" position.

7.5.12.3.2.4 Turn all other switches to "OFF" position.

7.5.12.3.2.5 Close sliding door to washer and push drain control to close.

7.5.12.3.2.6 While wash tank is filling (takes approximately one (1) minute), open and shut door to determine if automatic shut-off is functioning properly.

NOTE: OPENING DOOR SHALL SHUT-OFF ENTIRE MACHINE.

7.5.12.3.2.7. When water stops entering wash tank all switches shall be returned to the "OFF" position and the sliding door opened.

7.5.12.3.2.8 Place clean debris tray in the machine in upright position.

7.5.12.3.2.9 Push fused switch to turn on heating elements and the thermal cut-off. "RE-SET" button to insure that heating elements are in circuit and push. Allow temperature to stabilize at operating temperatures (Thermostat shall be initially set at 175°F).

NOTE: A - Operating temperatures above 200°F are not recommended.

B - Equipment should never be operated without a completely filled wash tank.

7.5.12.3.2.10 Vary temperature thermostat up to 190°F and allow temperature to re-stabilize to insure that temperatures are variable.

7.5.12.3.2.11 At this point check to see that timer controls are set as follows:

- A. Wash Timer - 2-1/2 minutes
- B. Rinse Timer - 2 minutes
- C. Final rinse timer - 1 minute.

7.5.12.3.2.12 Close sliding door. Washer should automatically start and progress through a complete wash and rinse cycle with jets spraying and tray cart traversing back and forth in machine. Timer lights should indicate which cycle is in progress and equipment should automatically stop at end of final rinse cycle.

7.5.12.3.2.13 Open and close sliding door. Paragraph 7.5.12.3.2.12 should automatically repeat in its entirety.

7.5.12.3.2.14 Operational test is now complete -
Deactivate all controls.

7.5.12.4 Data Review

Upon completion of all tests outlined in Section 7.5.12.3 the results shall be reviewed for compliance with Section 6.5.12.3 requirements.

6.5.15 Refrigerator

- 6.5.15.1 The two refrigerators obtained to fill this requirements are standard household type Frigidaire Model FPO-14T units having a separate freezing compartment.
- 6.5.15.2 The numbered dial inside the lower cabinet adjusts the inside temperature but there is no correlation between inside temperature and numbers on the dial. Acceptance of the unit is based upon demonstration that the internal temperature is maintained at $40 \pm 5^{\circ}\text{F}$ and that the freezing compartment maintains a temperature of less than 32°F .

6.5.16 Fume Hood

- 6.5.16.1 The Fume Hood is a thin wall, exhaust hood assembly four ft. wide, with a stainless steel interior and outlets for water, air gas, vacuum and electricity and is designed to exhaust gases thru ductwork to the outside of the facility.
- 6.5.16.2 The air velocity thru the hood shall be 850 fpm minimum.
- 6.5.16.3 A static pressure of not less than 0.625 inches of water shall be maintained between the ambient pressure and the exhaust scoop at the rear of the working surface.

7.5.15 Refrigerator

- 7.5.15.1 The refrigerators are located one each in the EAST OSE area and the Sterile Transfer Room.
- 7.5.15.2 Plug in the cord furnished into a utility 110 VAC outlet. Allow the refrigerator to stabilize in temperature for four hours with the internal control knob set at 4. Place a mercurial thermometer (0-100°F) rated at 2% accuracy or better on the middle shelf at an unobstructed location. Allow the temperature to stabilize for 10 minutes. Read and record the temperature. Place the thermometer in the freezing compartment and allow the temperature to stabilize for 10 minutes. Read and record the temperature.

7.5.16 Fume Hood

7.5.16.1 The fume hood is installed in the biology lab and the exhaust goes thru the overhead to a vent on the south wall of the building.

7.5.16.2 Measure and record the air velocity thru the hood.

Use the Gelman-Wallac Anemometer Model GGA2C (Item 4.8).

7.5.16.3 Measure and record the air pressure between the exhaust scoop and ambient.

It shall be in excess of 0.625 inches of water.

Use a Dwyer inclined, vertical Manometer, Model 400 (item 4.14).

6.5.17 Laminar Flow Bench
(Pure Aire Horizontal Flow Bench)

6.5.17.1 The "Pure Aire Horizontal Flow Bench" Model EG 4220, is a self contained laminar flow, work bench designed to provide clean, filtered, laminar flow air meeting U.S.A.F. T.O 00-25-203 and Federal Standard 209.

6.5.17.2 The Laminar Flow Bench will be certified upon verification of the level of illumination air velocity and effectiveness of the absolute filter.

6.5.17.3 Certification Requirements

6.5.17.3.1 Illumination of the lighting level when measured at the work surface shall be 125 ± 25 foot candles.

6.5.17.3.2 The air velocity as measured across the entire face of the absolute filter shall be 90 ± 20 fpm.

6.5.17.3.3 The "HEPA" filter shall be leak-checked by the performance of a standard "smoke" or "DOP" test. Any leaks detected by a photometer reading of 0.01% of the upstream smoke concentration shall be sealed off prior to certification.

7.5.17. Laminar Flow Bench - Certification Test Plan
(Pure Aire Horizontal Flow Bench)

7.5.17.1 Test Equipment & Test Requirements

The following listed equipment or an equipment item which is acceptable to Quality Assurance, shall be required in establishing compliance with Section 6.5.11.3

7.5.17.1.1 Weston Light Meter, Industrial Type

7.5.17.1.2 Recording Anemometer, Gelman-Wallac Model GGA2C.

7.5.17.1.3 Smoke Generator and Atomizing Nozzle, Royco Model WA, 18 cfm maximum capacity 0.3 Micron and smaller particle size.

7.5.17.1.4 Photometer, Sinclair Phoenix Particulate Counter, Model U 2000.

7.5.17.2 Preparation for Testing

The laminar flow bench shall be checked for visible damage to the bench or components prior to the initiation of the following tests which will be required for certification. Any defective components or visible damage shall be noted on the test report prior to commencing the tests. A complete vacuuming and cleaning of the unit shall have been conducted prior to testing. The power required for operation is 110 volt 60 cycle single phase. The power source shall be properly grounded and provided by standard 3-prong receptacle to receive the unit service cord (unit may be permanently wired if physical location is permanent.

7.5.17.2.1 Turn both light switch and blower switch to "ON" position.

7.5.17.2.2 Check to ascertain that all lights are on and that the blower is delivering air across the work station.

7.5.17.2.3 Allow unit to run for a minimum of 10 minutes and then conduct the certification tests as outlined below.

7.5.17.3 Testing Sequence and Operations

7.5.17.3.1 Illumination Test

7.5.17.3.1.1 The lighting level shall be checked with the light meter laying on the work bench surface.

7.5.17.3.1.2 The light meter shall be moved such that the entire area is scanned with a minimum of six (6) readings being recorded.

7.5.17.3.2 Velocity Test

7.5.17.3.2.1 The velometer and probe shall be set up and checked in accordance with manufacturer's instructions.

7.5.17.3.2.2 Velometer readings shall be recorded at a minimum of eight points, on a grid, across the face of the absolute filter.

7.5.17.3.2.3 In scanning the entire face of the filter any indication of a reading outside the specified tolerances shall be checked and recorded in addition to the selected grid points.

7.5.17.3.3 Filter Leak Test

7.5.17.3.3.1 The portable smoke generator shall be started and the required smoke concentration, for 100% deflection of the aerosol photometer, introduced to the plenum upstream of the Absolute filter. (28.8 scfm of undiluted concentration-minimum allowable concentration).

7.5.17.3.3.2 The entire downstream surface area of the absolute filter and all seals shall be scanned with the aerosol photometer.

7.5.17.3.3.3 Any photometer readings in excess of the maximum allowable readings shall result in voiding of the entire leak test until specific leaks are sealed.

7.5.17.3.3.4 When all photometer readings are within the allowable leakage rate the maximum reading noted shall be recorded.

7.5.17.4 Data Review

Upon completion of all tests outlined in Section 7.5.17.3 the results shall be reviewed for compliance with section 6.5.11.3 requirements.

APPENDIX - "B"

DATA SHEETS FOR TEST PROCEDURES

D A T A S H E E T

Single Door Steam Sterilizer (D-1)

Manufacturer: Wilmot Castle Company

Serial Number: _____

Equipment	Manufacturer	Model	Range	Last Date of Calif.	Signature
-----------	--------------	-------	-------	------------------------	-----------

Pressure Gauges calibrated	Date	Next Calib	Date
----------------------------	------	------------	------

7.5.3.2	Pressure Gauges checked	Pointer Reset	No Reset
---------	-------------------------	---------------	----------

7.5.3.3	Thermometer Check	Pointer Reset	No Reset
---------	-------------------	---------------	----------

7.5.3.4 Temperature, Vacuum and Pressure Recorder Chk.

Pens Adj.	No. Adj.
-----------	----------

7.5.3.5	Pressure Lock Adjustment Check	Adj. Chk. O.K.	Needed Adj.
---------	--------------------------------	----------------	-------------

7.5.3.6	Locking Bar Adjustment Check	Adj. Chk. O.K.	Needed Adj.
---------	------------------------------	----------------	-------------

Accepted _____ Date _____

D A T A S H E E T

ETO DECONTAMINATION CHAMBER (D-2 And D-5)

MANUFACTURE: WILMONT CASTLE COMPANY

SERIAL No.:

Test				Last Date	
<u>Equipment</u>	<u>Manufacture</u>	<u>Model</u>	<u>Range</u>	<u>Of Calibration</u>	<u>Signature</u>
1.	_____	_____	_____	_____	_____
2.	_____	_____	_____	_____	_____
3.	_____	_____	_____	_____	_____
4.	_____	_____	_____	_____	_____

Pressure Gauges Calibrated _____ Next Calibration _____
Date Date

Paragraph	Q.A. Signature
7.5.4.2 Sterilock Interlocking Door Checked & Accepted	_____
7.5.4.2.1 Locking Bar Adjustment Checked & Accepted	_____
7.5.4.3 Vacuum Pump Operation Checked & Accepted	_____
7.5.4.4 Recorder Pen Calibration Checked & Accepted	_____
7.5.4.6 Exposure Timer Checked & Accepted	_____
7.5.4.7 Humidity Control Operation Checked & Accepted	_____
7.5.4.8 "Install Gas Cylinder" Pilot Light Checked & Accepted	_____
7.5.4.9 Temperature Controller Checked and Accepted	_____

COMMENTS:

DATA SHEET

TWO DOOR STEAM STERILIZER (D-3 and D-4)

Manufacture: Wilmot Castle Company

Serial No.: _____

<u>Test Equipment</u>	<u>Manufacture</u>	<u>Model</u>	<u>Range</u>	<u>Last Date of Calibration</u>	<u>Signature</u>
1.					
2.					
3.					
4.					
5.					

Pressure Gauges Calibrated _____ Next Calibration _____
Date Date

Paragraph

7.5.5.2 Pressure Gauges Checked _____
Pointer Reset No Reset

		<u>Q. A. Signature</u>
7.5.5.3.1	Switch Assembly Operation Checked & Accepted	
7.5.5.3.2	Bellows to Indicator Operation Checked & Accepted	
7.5.5.3.3	Pen Calibration Checked and Accepted	
7.5.5.4.1	Pressure Switch Operation Checked & Accepted	
7.5.5.4.2	Sterilizing Timer Tol. Checked and Accepted	
7.5.5.4.3	Drying Timer Checked and Accepted	
7.5.5.5	Sterilock Interlocking Doors Operation Accepted	
7.5.5.5.1	Pressure Lock Operation Checked and Accepted	
7.5.5.5.2	Locking Bar Adjustment Checked and Accepted	

DATA SHEET - TWO-TON ELECTRIC HOIST

7.5.6.3 - Testing Sequence and Operations.

7.5.6.3.1	11 Pitch Length	
	Max. Allowable	Actual
Check #1		
Check #2		
Check #3		

4

7.5.6.3.2 & 3 - Visual Inspection

7.5.6.3.2	ITEM	Q.A. SIGNATURE
a.		
b.		
c.		
7.5.6.3.3		
a.		
b.		
c.		

7.5.6.3.4	Distance Checked (ft)	Time (Minutes)	Rate (fpm)
Raise			
Lower			

7.5.6.3.5 Hoist Motor Brake -

Automatic shut-off functioning properly Yes ☐ No ☐

7.5.6.3.6 Proof Load

	Rated Load	Max Possible Error
Tare Wt. (handling equip.) =		
+ Net Test Load =		
Proof Load Applied =		
(must not exceed 4,000#)		

Proof load held stationary by hoist for at least 30 seconds after stopping? Yes ☐ No ☐

7.5.6.3.7 Pendant raise-lower buttons in agreement with wall mounted controls? Yes ☐ No ☐

CONCLUSION OF DATA REVIEW

1. Certification granted ☐ 2. Certification not granted ☐

Comments: _____

Certification by: _____ Date: _____

Quality Assurance Approval by: _____ Date: _____

D A T A S H E E T
TWO DOOR DRY HEAT STERILIZER

7.5.7 Manufacturer _____
 Model Number _____
 Serial Number _____

7.5.7.2 Remote Thermocouple
 Make _____
 Model _____ Range _____ to _____
 Date last calibration _____
 Date next calibration _____

7.5.7.2.1 Internal Dimensions are height _____ in. Width _____ in. Depth _____ in.

7.5.7.2.3 Dial setting (125°C)
 Built in thermometer reading _____
 Remote indicating thermometer reading _____

 Dial Setting (final) _____
 (ex. 125.2)
 Built-in Thermometer reading _____
 Remote indicating thermometer reading _____

7.5.7.2.4 The alarm functions
 Dial setting when alarm starts _____
 Built-in thermometer reading _____
 Remote indicating thermometer _____

7.5.7.2.5. Dial Setting (175°C) _____
 Built-in thermometer reading _____
 Remote indicating thermometer _____
 Dial setting (2x. 175.4) _____
 Built-in thermometer reading _____
 Remote indicating thermometer _____

7.5.7.2.6. Dial Setting (from 7.5.7. 2.1.) _____
 Built-in thermometer reading _____
 Remote thermometer reading _____

7.5.7.2.7. Dial setting (from 7.5.7.2.3.) _____
 Built-in thermometer reading _____
 Remote indicating thermometer reading _____

7.5.7.2.8. Dial Setting (300°C) _____
 Final dial setting (example 300.4°C) _____
 Built-in thermometer reading _____
 Remote indicating thermometer reading _____

D A T A S H E E T

GLASS DRYER

7.5.8 Manufacturer _____

Model Number _____

Serial Number _____

7.5.8.2 Remote Thermocouple _____

Make _____

Model _____

Range _____ to _____

Date last calibration _____

Date next calibration _____

7.5.8.2.1 Internal Dimensions are height _____ in. Width _____ in. Depth _____ in.

7.5.8.2.3 Dial setting (80°C)

Built in thermometer reading _____

Remote indicating thermometer reading _____

Dial Setting (final) _____
(ex. 80.2)

Built-in Thermometer reading _____

Remote indicating thermometer reading _____

7.5.8.2.4 The alarm functions

Dial setting when alarm starts _____

Built-in thermometer reading _____

Remote indicating thermometer _____

7.5.8.2.5 Dial Setting (175°C) _____
Built in thermometer reading _____
Remote indicating thermometer _____
Dial setting (ex. 175.4) _____
Built in thermometer reading _____
Remote indicating thermometer _____

7.5.8.2.6 Dial Setting (from 7.5.8.2.1) _____
Built in thermometer reading _____
Remote thermometer reading _____

7.5.8.2.7 Dial setting (from 7.5.8.2.3) _____
Built in thermometer reading _____
Remote indicating thermometer reading _____

7.5.8.2.8 Dial Setting (300°C) _____
Final dial setting (example 300.4°C) _____
Built in thermometer reading _____
Remote indicating thermometer reading _____

7.5.9.1 - Test Equipment (Q.A. Signature required on equivalent items or exceptions only)

Paragraph	Equipment type	Manufacturer	Model	Serial	Range	Accuracy	Last date of Calibration	Signature
7.5.9.1.1								
7.5.9.1.2								
7.5.9.1.3								
7.5.9.4								

Comments by Q.A. if any

7.5.9.2 - Preparation for Testing (Q.A. Signature required on each item prior to proceeding)

Paragraph	I T E M	Q.A. Signature
7.5.9.2.1	Power Supply checked and acceptable	
7.5.9.2.2	Refrigeration Unit free to operate - checked and acceptable	
7.5.9.2.3	Rotor type and seating acceptable	
7.5.9.2.4	Timer set-up acceptable	
7.5.9.2.5	Strobatac set-up acceptable	
7.5.9.2.6	Temperature sensing set-up acceptable	

7.5.9.3 Testing Sequence & Operations

7.5.9.3.1 Temperature Control & Range Certification

Paragraph	(Dial Setting)	Time	Room Ambient	Equip. Temp. Standard	Equip. Temp. Indicator	E R R O R Dial Indicator	Repeatability Calculated
7.5.9.3.1.1		-					—
7.5.9.3.1.6		20					—
7.5.9.3.1.7	-20	40					—
7.5.9.3.1.8	-20	—					—
	-10	—					—
	-0	—					—
	-10	—					—
	20	—					—
	30	—					—
	40	—					—
	30	—					
	20	—					
	10	—					
	0	—					
	-10	—					
	-20	—					

7.5.9.3.2 - Automatic Timer Certification

Paragraph	Data I.D.	D A T E											
			20	40	60	80	100	120	100	80	60	40	20
7.5.9.3.2.1.1	Auto Timer Setting (Min.)												
7.5.9.3.2.1.2	Actual Time (Standard) (Seconds/Min.)												
	E R R O R (Calculated)												
	Repeatability Calculated												

7.5.9.3.3 & 7.5.9.3.4 - Speed Indicator, Control and Range Certification

Paragraph	Data I.D.	D A T E										
7.5.9.3.4.1.1	Speed Selector Dial Setting (rpm)	3000	6000	9000	12000	15000	18000	15,000	12,000	9000	6000	3000
7.5.9.3.4.1.2	Strobotac Reading (rpm)											
7.5.9.3.4.1.3	Tachometer Reading (rpm)											
	E R R O R											
	Dial Tach											
7.5.9.3.4.1.4	Repeatability (Calculated)											

ACCELERATION TIME CHECK

Paragraph	Data I.D. Speed Selector Setting (rpm)	Data
7.5.9.3.4.2		18000
7.5.9.3.4.4.1	Max. Attained Speed, Tach. (rpm)	
7.5.9.3.4.4.2	Time Req'd. (Secs.)	

BRAKING TIME CHECK

Paragraph	Data I.D. Speed Selector Setting (rpm)	Data
7.5.9.3.4.2		18,000
7.5.9.3.4.6.1	Initial Speed, Tach. (rpm)	
7.5.9.3.4.6.2	Time Req'd. Secs.)	

TESTING STARTED, DATE _____ Hour _____

TESTING COMPLETED, DATE _____ Hour _____

TESTS CONDUCTED BY _____
(Signature)

TESTS WITNESSED BY _____
Q. A. Signature

7.5.9.4 - Data Review

	MAXIMUM ERROR		REMARKS
	Allowable	Actual (Data)	
7.5.9.3.1			
Dial	+1.0°C		
Indicator	+1.0°C		
Repeatability	+1.0°C		Repeatability must be within equipment accuracy.
7.5.9.3.2			
Timer	+2 Min.		
Repeatability	+1%		% based actual time interval (standard)
7.5.9.3.3 & 4			
Dial	+3%		% based on actual rotor rpm (strobatac)
Tachometer	+3%		% based on actual rotor rpm (strobatac)
Repeatability	+1%		% based on actual rotor rpm (strobatac)
7.5.9.3.4 (cont'd)	Required	Actual (Data)	REMARKS
Acceleration Time	105 Sec.		
Braking Time	265 Sec.		

Conclusion of Data Review:

1. Certification Granted - ☐; 2. Certification Not Granted - ☐
 (full compliance) (restricted use)

Comments: _____

Certification by: _____ Date: _____

Quality Assurance Approval: _____ Date: _____

D A T A S H E E T - Incubator, Humidity Controlled

7.5.10.1 Test Equipment (Q.A. Signature required on equivalent items or exceptions only)

Paragraph	Equipment Type	Manufacturer	Model	Serial	Range	Accuracy	Last Date of Calibration	Q.A. Signature
7.5.10.1.1								
7.5.10.1.2								
7.5.10.1.3								

Comments by Q.A., if any

7.5.10.2 - Preparation for Testing (Q.A. Signature required on each item prior to proceeding)

Paragraph	I T E M
7.5.10.2.1	
7.5.10.2.2	
7.5.10.2.3	

D A T A S H E E T - I N C U B A T O R, H U M I D I T Y C O N T R O L L E D

7.5.10.3 - Testing Sequence & Operations

7.5.10.3.1, 3 & 4 - Temperature Control, & Range Certification, Humidity Control and Indicator Certification - Hygrometer Indicator Certification.

Paragraph	Temp Control Setting °C	Hum. Control Setting °C	Room Ambient DB WB	Equip. Temperature (Standard)	Equip. Humidity (Standard)	Incubator Hygrometer Reading	Incubator Temperature Eqpt. D.B.	Ambiant R.H. (Calculated)
7.5.10.3.1.5	—	—		—	—	—	—	
7.5.10.3.1.10	32°	23.6°						
7.5.10.3.1.11	37°	32.2°						
	55°	32.2°						

7.5.10.3.2 Limitstat Certification

7.5.10.3.2.2 Potential difference between terminals 17 and 14 = _____.

Testing Started, Date _____ Hours _____ Tests Conducted By: _____ Signature _____
 Testing Started, Date _____ Hours _____ Tests Witnessed By: _____ (Q. A. Signature)

D A T A S H E E T - I N C U B A T O R , H U M I D I T Y C O N T R O L L E D

7.5.10.4 - DATA REVIEW

7.5.10.3.1	Maximum Error		REMARKS
	Allowable	Actual Data	
Dial Indicator	$\pm 0.5^{\circ}\text{C}$		
Internal Thermometer			
7.5.10.3.2			
Limitstat			
7.5.10.3.3			
Dial Indicator	$\pm 0.5^{\circ}\text{C}$		
7.5.10.3.4			
Humidity Indicator	$\pm 5\%$		

CONCLUSION OF DATA REVIEW

1. Certification Granted - ☐; 2. Certification Not Granted ☐;

COMMENTS:

Certification By: _____, Date: _____

Quality Assurance Approval: _____, Date: _____

D A T A S H E E T - Laminar Flow Bench

7.5.11.1 - Test Equipment (Q.A. Signature required on equivalent items or exceptions only)

Paragraph	Equipment type	Manufacturer	Model	Serial	Range	Accuracy	Last Date of Calibration	Q.A. Signature
7.5.11.1								
7.5.11.2								
7.5.11.1.3								
7.5.11.1.4								

Comments by Q.A. if any _____ ,

7.5.11.2 - Preparation for Testing (Q.A. Signature required on each item prior to proceeding)

Paragraph	I T E M	Q.A. Signature
7.5.11.2.1		
7.5.11.2.2		
7.5.11.2.3		

DATA SHEET - Invasive Flow Patch

7.5.11.3 - Testing Sequence and Operations

7.5.11.3.1 Illumination Test

7.5.11.3.1.2	Loc. #1	Loc. #2	Loc. #3	Loc. #4	Loc. #5	Loc. #6
Illumination (foot candles)						

7.5.11.3.2 Velocity Test

7.5.11.3.2.2	Loc.-1	Loc.-2	Loc.-3	Loc.-4	Loc.-5	Loc.-6	Loc.-7	Loc.-8
Velocity (ft./m.n.)								

7.5.11.3.2.3 Scan Readings which are out of tolerance by Grid location

Velocity (ft/Min.)								
-----------------------	--	--	--	--	--	--	--	--

7.5.11.3.3 Filter Leak Test

7.5.11.3.3.2 Maximum Reading = % deflection - - Allowable? Yes ☐, No ☐

7.5.11.3.3.3 Maximum Reading after repair, if req'd. = % deflection - Allowable? Yes ☐, No ☐

D A T A S H E E T - Laminar Flow Bench

7.5.11.4 Data Review

7.5.11.3.1	MIN/MAX. READING	
	Allowable	Actual
Illumination	200 ft. cd. min.	
7.5.11.3.2	_____	
Velocity	95 ± fpm	
7.5.11.3.3	_____	
Leakage	0.01% Max.	

CONCLUSION OF DATA REVIEW:

1. Certification granted - ☐ ; 2. Certification Not Granted - ☐

COMMENTS:

Certification by: _____ Date: _____

Quality Assurance Approval: _____, Date: _____

D A T A S H E E T - Laboratory Glassware Washer

7.5.12.1 - Test Equipment (Q.A. Signature required on equivalent items or exceptions only)

Paragraph	Equipment Type	Manufacturer	Model	Serial	Range	Accuracy	Last date of calibration	Q.A. Signature
7.5.12.1.1								
7.5.12.1.2								
7.5.12.1.3								

Comments by Q. A., if any

7.5.12.2 - Preparation for Testing (Q.A. Signature required on each item prior to proceeding)

Paragraph	I T E M	Q.A. Signature
7.5.12.2.1		
7.5.12.2.2.1		
7.5.12.2.2.2		
7.5.12.2.2.3		
7.5.12.2.2.4		
7.5.12.2.2.5		

D A T A S H E E T - Laboratory Glassware Washer

7.5.12.3 - Test Sequence and Operations

7.5.12.3.1 - Temperature Indicator

Paragraph	T 1	T2	T3	T4	T5
7.5.12.3.1.1					
Ambiant T.					
7.5.12.3.1.2					
Ambiant T.					
CORRECTED TEMPERATURES					
7.5.12.3.1.1					
7.5.12.3.1.2					

7.5.12.3.2 Operational Test

7.5.12.3.2.6	Automatic shut-off functioning properly	YES <input type="checkbox"/>	NO <input type="checkbox"/>
7.5.12.3.2.9	Stable temperature at 175°F	YES <input type="checkbox"/>	NO <input type="checkbox"/>
7.5.12.3.2.10	Stable temperature at 190°F	YES <input type="checkbox"/>	NO <input type="checkbox"/>
7.5.12.3.2.11	(Adjust to required setting if required)	YES <input type="checkbox"/>	NO <input type="checkbox"/>
A. Wash Timer	Set at 2-1/2 Minutes.	YES <input type="checkbox"/>	NO <input type="checkbox"/>
B. Rinse Timer	Set at 2 Minutes	YES <input type="checkbox"/>	NO <input type="checkbox"/>
C. Final Rinse Timer	Set at 1 Minute	YES <input type="checkbox"/>	NO <input type="checkbox"/>

D A T A S H E E T - Laboratory Glassware Washer

7.5.12.3.2 Operational Test (Cont'd)

7.5.12.3.2.12 Wash & Rinse Cycle completed satisfactorily YES ☐ NO ☐

7.5.12.3.2.13 Wash & Rinse Cycle completed satisfactorily YES ☐ NO ☐

7.5.12.4 Data Review

7.5.12.3.1	Maximum Error		R E M A R K S
	Allowable	Actual	
Temp. Indicator	± 6.6°F		

7.5.12.3.2 Operational Test

7.5.12.3.2.6	Allowable Time	Actual Time	R E M A R K S
Wash Tank	Approx. 1 min.		
Fill Time			

Door Shut Off Functioning properly? YES ☐ NO ☐

7.5.12.3.2.9 & 10 Thermostat functioning properly? YES ☐ NO ☐

7.5.12.3.2.11 Timer controls set properly? YES ☐ NO ☐

7.5.12.3.2.12 & 13. Wash & Rinse Cycle functioning properly? YES ☐ NO ☐

D A T A S H E E T - Laboratory Glassware Washer

CONCLUSION OF DATA REVIEW

1. Certification Granted - ☐ 2. Certification Not Granted - ☐

COMMENTS:

Certification By: _____ Date: _____

Quality Assurance Approval _____ Date: _____

D A T A S H E E T

FUME HOOD

Manufacturer _____

Model No. _____

Serial No. _____

General Appearance _____

Services Operating _____

7.5.16.2 Air Velocity _____ (850 Minimum fpm)

7.5.16.3 Air Pressure _____ 0.625 Minimum.

Test Equipment Used _____

Accepted _____ Date _____

AR/cs

D A T A S H E T - Laminar Flow Bench
(Pure Aire Horizontal Flow Bench)

7.5.17.1 - Test Equipment (Q.A. Signature required on equivalent items or exceptions only)

Paragraph	Equipment type	Manufacturer	Model	Serial	Range	Accuracy	Last Date of Calibration	Q.A. Signature
7.5.17.1								
7.5.17.2								
7.5.17.1.3								
7.5.17.1.4								

COMMENTS by Q. A. if any

7.5.17.2 - Preparation for Testing (Q.A. Signature required on each item prior to proceeding).

Paragraph	I T E M	Q.A. Signature
7.5.17.2.1		
7.5.17.2.2		
7.5.17.2.3		

D A T A S H E E T - Laminar Flow Bench

7.5.17.3 - Testing Sequence and Operations

7.5.17.3.1 Illumination Test

7.5.17.3.1.2	Loc. #1	Loc. #2	Loc. #3	Loc. #4	Loc. #5	Loc. #6
Illumination (Foot Candles)						

7.5.17.3.2 Velocity Test

7.5.17.3.2.2	Loc. -1	Loc.-2	Loc.-3	Loc.-4	Loc.-5	Loc.-6	Loc.-7	Loc.-8
Velocity (ft/min.)								

7.5.17.3.2.3 Scan Readings which are out of tolerance by Grid location

Velocity Ft/Min								
--------------------	--	--	--	--	--	--	--	--

7.5.17.3.3 Filter Leak Test

7.5.17.3.3.2 Maximum Reading= _____ % Deflection - - Allowable? Yes ☐, No ☐

7.5.17.3.3.3 Maximum Reading after repair, if req'd. = _____ % Deflection - Allowable? Yes ☐ No ☐

D A T A S H E E T - Laminar Flow Bench

7.5.17.4 Data Review

	MIN/MAX. READING		REMARKS
	Allowable	Actual	
7.5.17.3.1 Illumination	125 ± 25 ft. cd.		
7.5.17.3.2	-----		
Velocity	90 ± 20 fpm		
7.5.17.3.3	-----		
Leakage	0.01% Max.		

CONCLUSION OF DATA REVIEW:

1. Certification granted - ☐ ; 2. Certification not granted - ☐
(Restricted use)

Comment: _____

Certification by: _____, Date _____

Quality Assurance Approval: _____, Date _____

MONTHLY MONITORING
DATA SHEET-DRESSING ROOM #138

Instrumentation Used:

Instrument	Model No.	Serial No.	Last Calibrated	Next Calibrated

Filter Bank

Filters free of any leaks and accepted.

<u>last date</u>	<u>accepted</u>
<u>date</u>	<u>initials</u>

MONTHLY MONITORING

DATA SHEET-DRESSING ROOM #138

Air Velocity Test

_____ F.P.M. Max. (120) _____ F.P.M. Min. (80)

Position

1 _____ F.P.M.

2 _____ F.P.M.

3 _____ F.P.M.

4 _____ F.P.M.

5 _____ F.P.M.

6 _____ F.P.M.

Average _____ F.P.M.

Air Pressure History

Air Pressure at 0800 _____ (0.30 to 0.325)

1200 _____ (0.30 to 0.325)

1600 _____ (0.30 to 0.325)

Remarks: _____

Dry Bulb Temperature Tests

Dry bulb temperature as recorded by Honeywell Recorder.

_____ (77 °F.) _____ (67 °F.)
Max. Min.

_____ Date
Initials

MONTHLY MONITORING

DATA SHEET-DRESSING ROOM #138

Temperature Test in Room #138

_____ (77°F.) _____ (67°F.)
Max. Min.

_____ Date
Initials

Positions

1 _____ °F.
2 _____ °F.

Relative Humidity Test

Relative humidity as recorded by Honeywell Recorder.

_____ (45 %) _____ (40 %)
Max. Min.

_____ Date
Initials

Relative Humidity Test in Room #138

_____ (45 %) _____ (40 %)
Max. Min.

_____ Date
Initials

Position

1 _____ %
2 _____ %

MONTHLY MONITORING

DATA SHEET-DRESSING ROOM #138

Particle Count

Counter Calibrated

Initials

Date

Data Obtained

Location _____ Total Count _____

Attach digital readout data obtained from particulate counter to this data sheet.

Monthly Monitoring Completed

Accepted

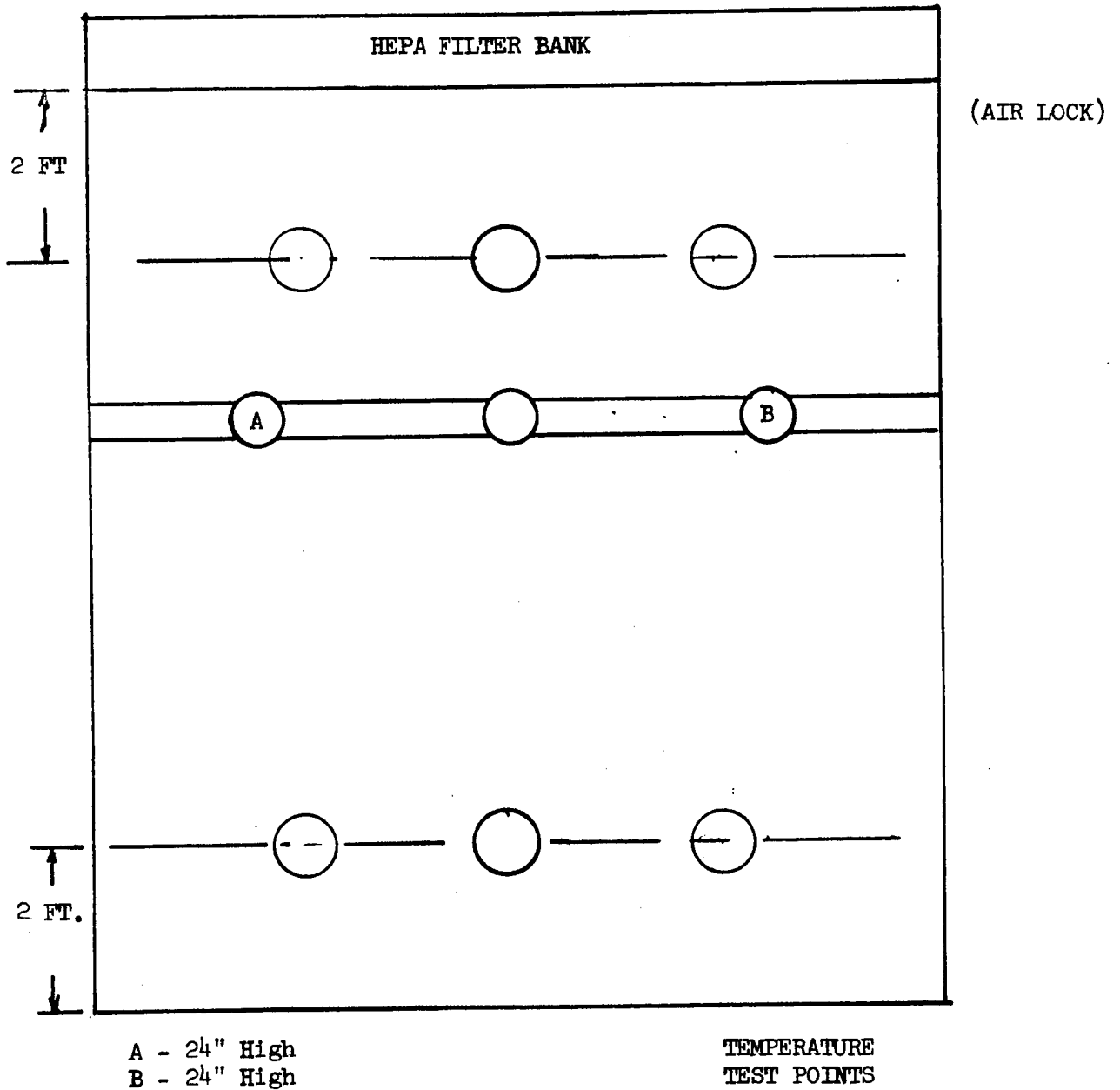
Quality Control

Date

Remarks: _____

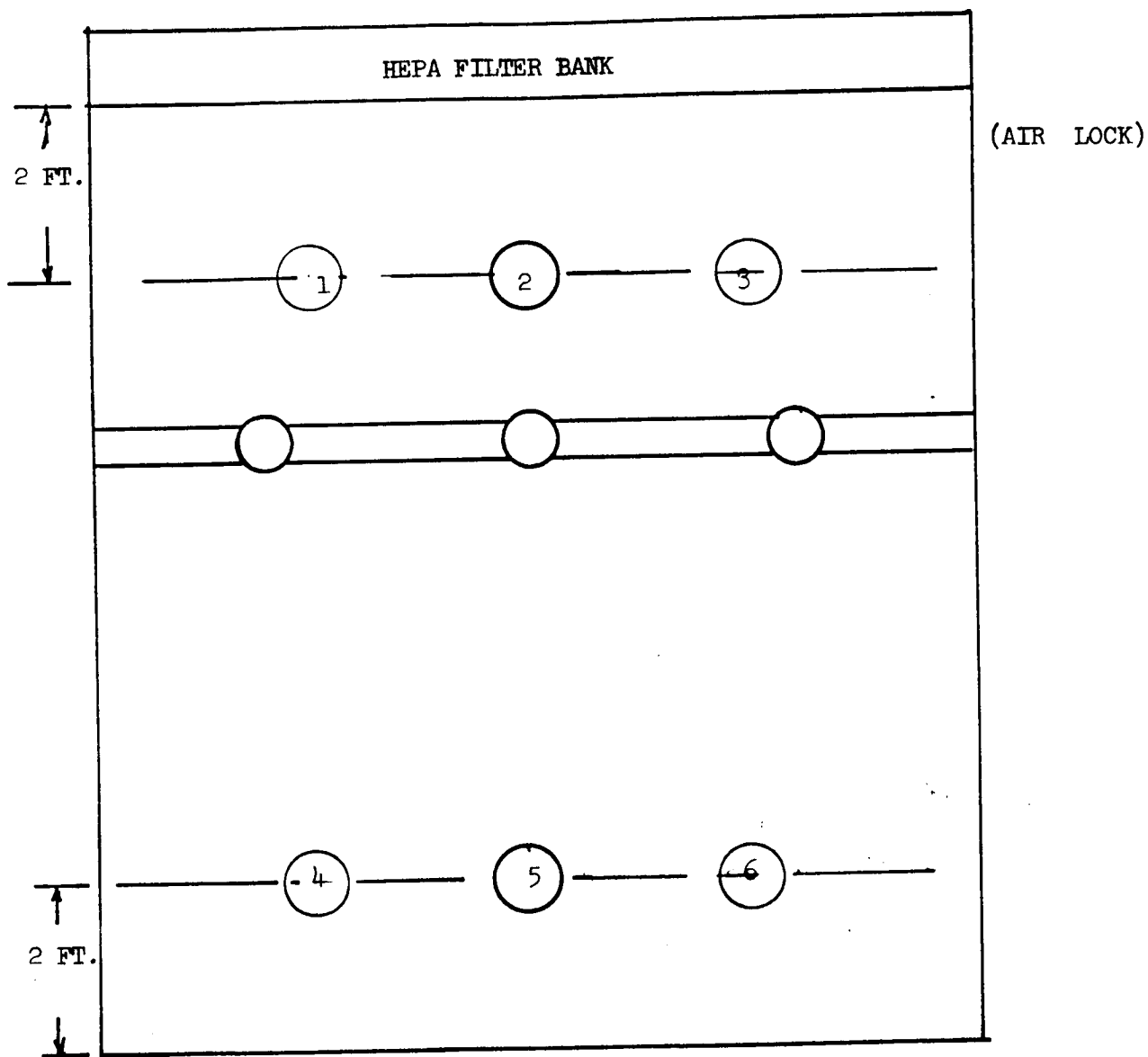
MONTHLY MONITORING
DATA SHEET - DRESSING ROOM #138

NORTH



MONTHLY MONITORING

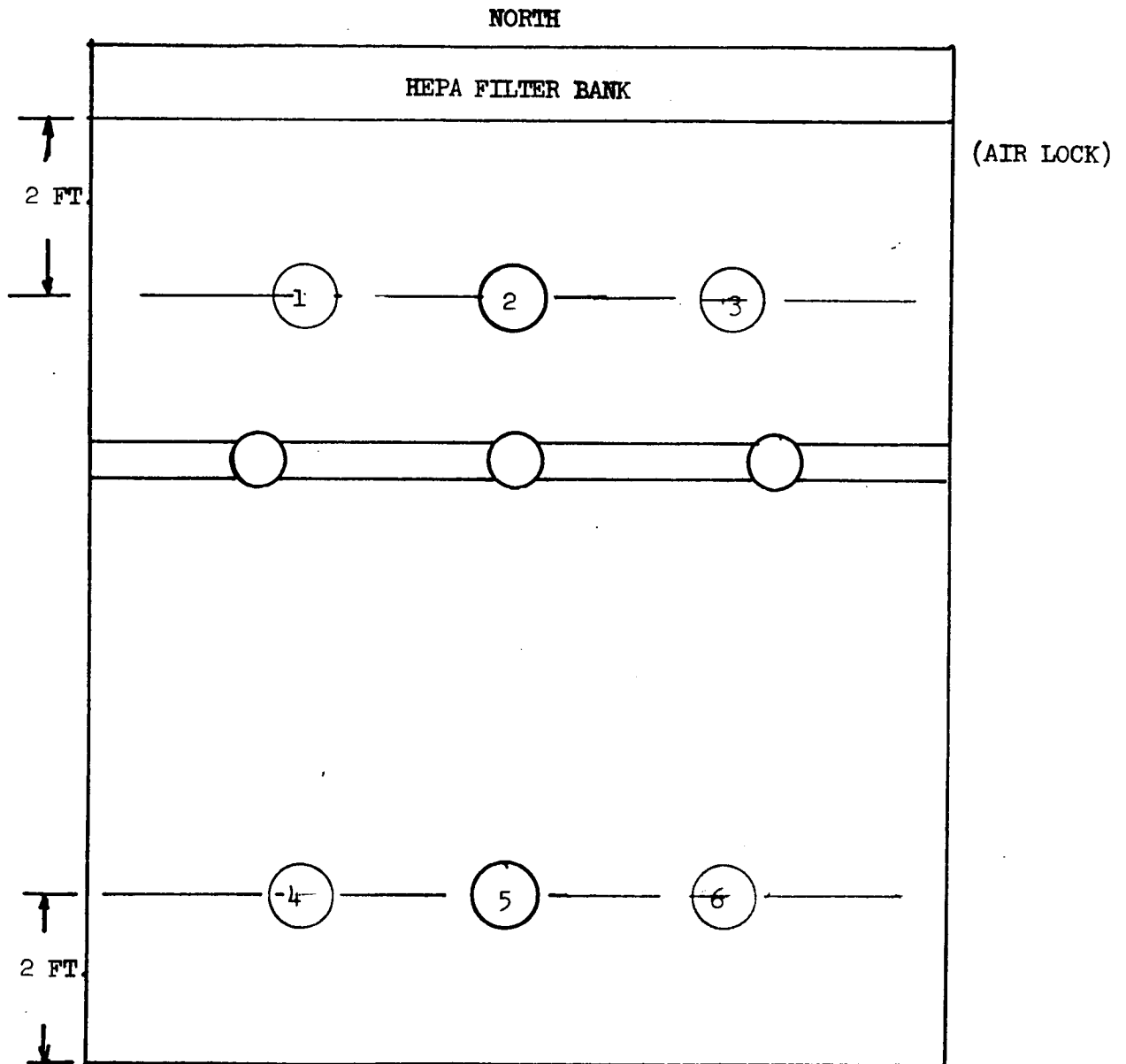
DATA SHEET - DRESSING ROOM #138



AIR VELOCITY TEST POINTS.

- 1 - 24" High
- 2 - 48" High
- 3 - 72" High
- 4 - 72" High
- 5 - 36" High
- 6 - 24" High

MONTHLY MONITORING
DATA SHEET - DRESSING ROOM #138

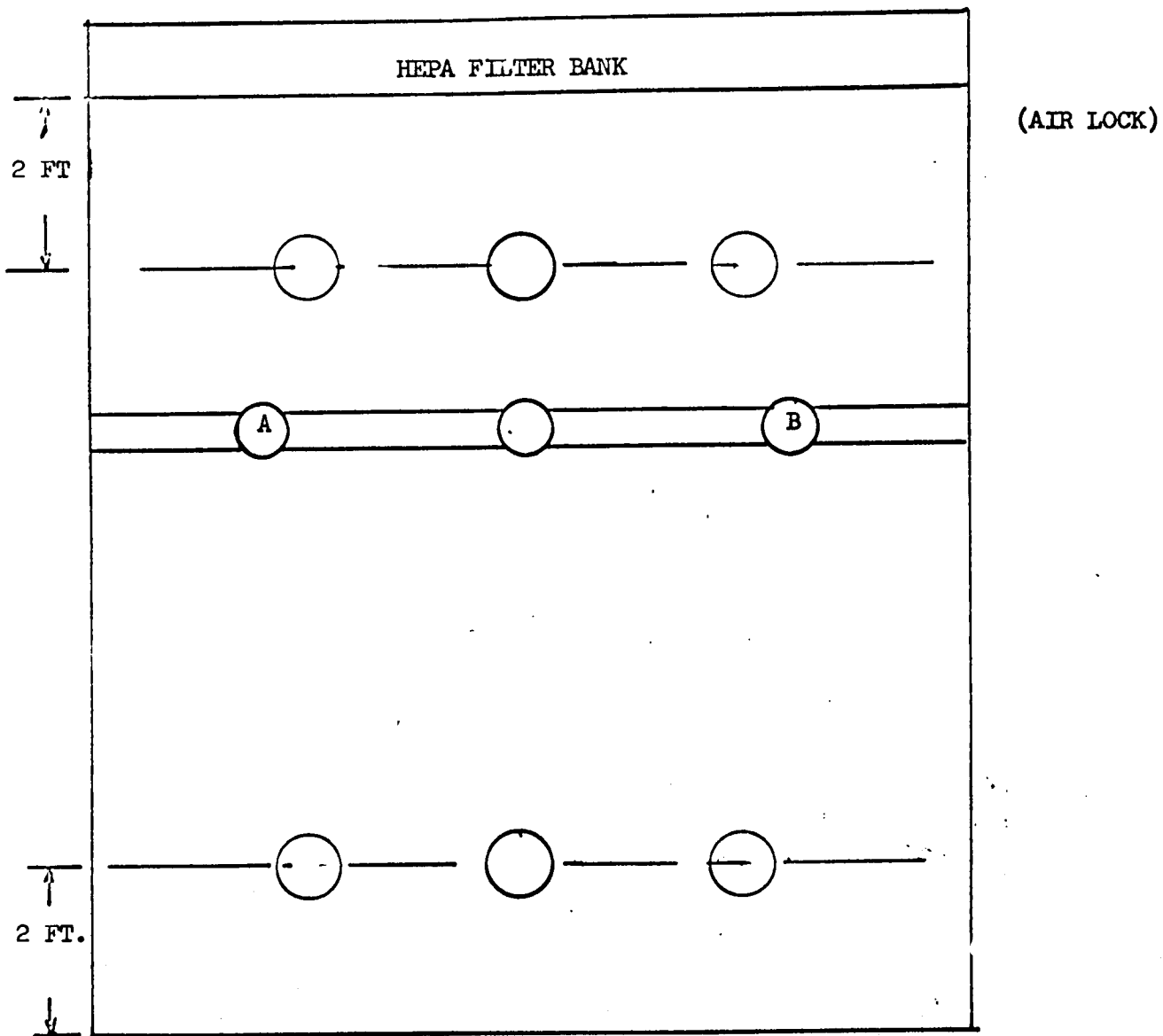


MEASUREMENTS 45"
ABOVE THE FLOOR.

PARTICULATE COUNT TEST POINTS.

MONTHLY MONITORING
DATA SHEET - DRESSING ROOM #138

NORTH



A - 24" High
B - 24" High

HUMIDITY
TEST POINTS.

MONTHLY MONITORING

DATA SHEET - AIR LOCK #139

Instrumentation Used

Instrument	Model No.	Serial No.	Last Calibration	Next Calibration

MONTHLY MONITORING

DATA SHEET - AIR LOCK #139

Dry Bulb Temperature Tests.

Dry bulb temperature as recorded by Honeywell recorder.

____ (77 °F.) ____ (67 °F.)
Max. Min.

Initials Date

Temperature Test in Room #139

____ (77° F.) ____ (67 °F.)
Max. Min.

Initials Date

Relative Humidity Tests.

Relative humidity as recorded by Honeywell recorder.

____ (45 %) ____ (40 %)
Max. Min.

Initials Date

Relative Humidity Test in Room #139.

____ (45 %) ____ (40 %)
Max. Min.

Initials Date

MONTHLY MONITORING
DATA SHEET - AIR LOCK #139

Air Pressure History:

Air Pressure at 0800 _____ (0.25 to 0.275)
1200 _____ (0.25 to 0.275)
1600 _____ (0.25 to 0.275)

Remarks: _____

Particle Count:

Counter Calibrated

Initials

Date

Data Obtained

LOCATION	TOTAL COUNT
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Attach digital readout data obtained from particulated counter to this data sheet.

Monthly Monitoring Completed

Accepted

Quality Control

Date

Remarks: _____

MONTHLY MONITORING

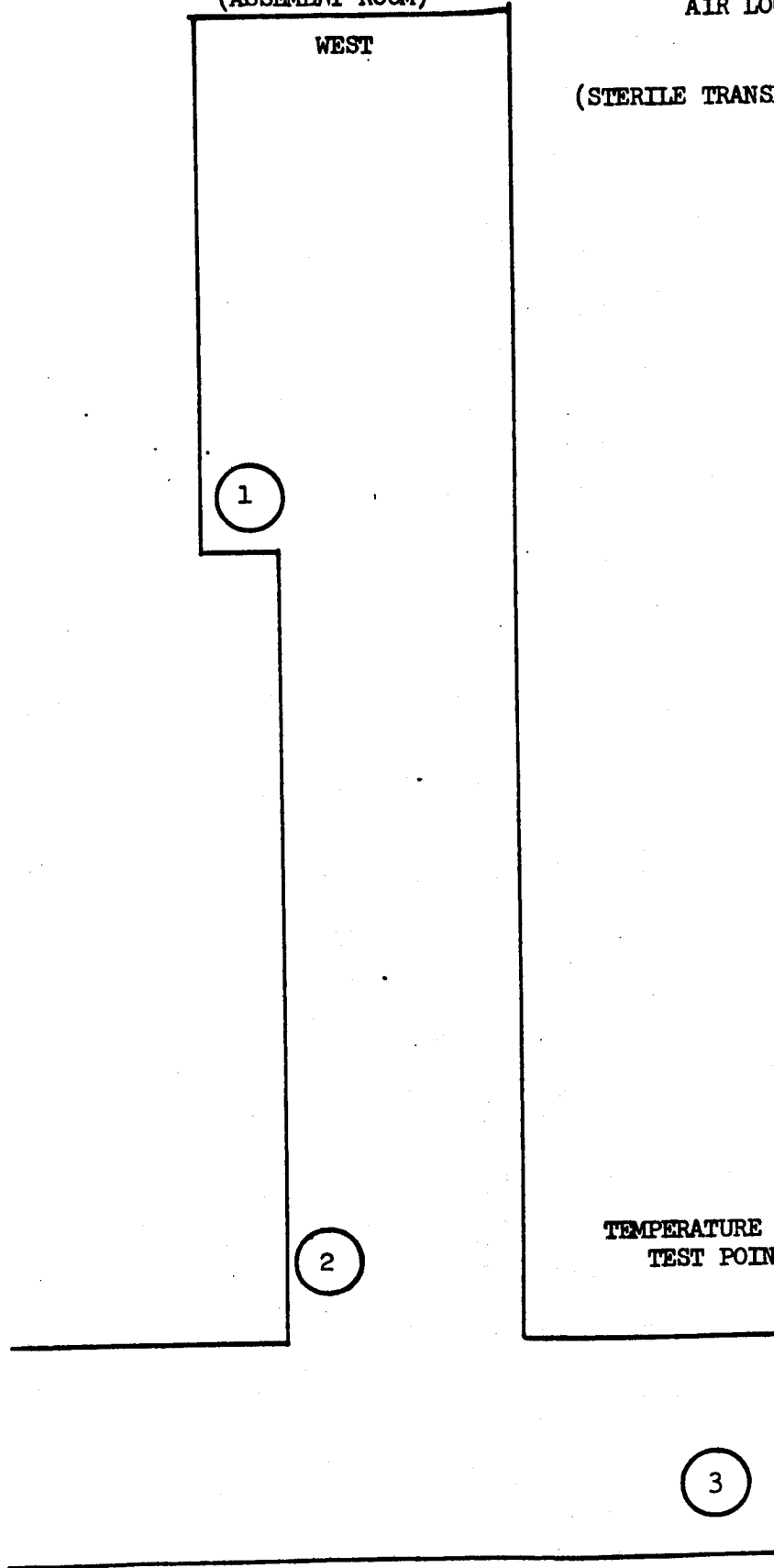
DATA SHEET

AIR LOCK #139

(ASSEMBLY ROOM)

WEST

(STERILE TRANSFER)



TEMPERATURE AND HUMIDITY
TEST POINTS.

ALL TEST POINTS 48"
ABOVE THE FLOOR.

(ASSEMBLY ROOM)

MONTHLY MONITORING
DATA SHEET - AIR LOCK #139

(STERILE TRANSFER)

WEST

1

2

3

PARTICULATE COUNT
TEST POINTS.

MONTHLY MONITORING

DATA SHEET-ASSEMBLY ROOM #140

Instrumentation Used:

Instrument	Model No.	Serial No.	Last Calibration	Next Calibration

Filter Bank

Filters free of any leaks and accepted.

Last Date

Accepted

Next Test Required:

Date

Initials

MONTHLY MONITORING

DATA SHEET-ASSEMBLY ROOM #140

Dry Bulb Temperature:

Dry bulb temperature as recorded on Honeywell recorder.

_____ (77 °F) _____ (67 °F)
Max. Min.

_____ _____
Initials Date

Temperature Test in Room #140.

_____ (77 °F) _____ (67 °F)
Max. Min.

_____ _____
Initials Date

Position	Reading
1	_____
2	_____
3	_____
4	_____

Relative Humidity Test.

Relative humidity as recorded on Honeywell recorder.

_____ (45 %) _____ (40 %)
Max. Min.

_____ _____
Initials Date

DATA SHEET - ASSEMBLY ROOM #140

Min. (40%)

Date

1. _____
2. _____
3. _____
4. _____

Date _____

Total Count

B-44

DATA SHEET - ASSEMBLY ROOM #140

Position

6 Ft. High
F.P.M.

25 Ft. High
F.P.M.

F.P.M. MAXIMUM (95) F.P.M. MINIMUM (55)

Average	F.P.M.
---------	--------

Air Pressure at 0800 (0.40 to 0.425)

1200 (0.40 to 0.425)

1600 (0.40 to 0.425)

Remarks: _____

MONTHLY MONITORING COMPLETED

Accepted
Quality Control

Date

Remarks: _____

MONTHLY MONITORING

(ETO CHAMBER)

DATA SHEET - ASSEMBLY ROOM #140

NORTH

	A	B	C	D	E	F	G	H
1								
2								
3		○				○		
4								
5								
6								
7		○				○		
8								
9								
10								

(OSE)

TEMPERATURE AND RELATIVE HUMIDITY
TEST POINTS.

NORTH

	A	B	C	D	E	F	G	H
1								
2		○		○		○		
3								
4		○		○		○		
5								
6		○		○		○		
7								
8		○		○		○		
9								
10								

(OSE)









































AIR VELOCITY TEST POINTS

MONTHLY MONITORING

DATA SHEET - ASSEMBLY ROOM #140

(ETO CHAMBER)

NORTH

	A	B	C	D	E	F	G	H
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

(OSE)

PARTICULATE COUNT TEST POINTS.

MONTHLY MONITORING

DATA SHEET - STERILE TRANSFER ROOM #141

Instrumentation Used

Instrument	Model No.	Serial No.	Last Calibrated	Next Calibration

Dry Bulb Temperature Tests:

Dry Bulb Temperature as recorded on Honeywell Recorder.

_____ (77 °F.) _____ (67 °F.)
Max. Min.

_____ Date
Initials

Temperature Tests in Room #141

_____ (77 °F.) _____ (67 °F.)
Max. Min.

_____ Date
Initials

Position Reading

_____	_____
_____	_____
_____	_____

MONTHLY MONITORING

DATA SHEET - STERILE TRANSFER ROOM #141

Relative Humidity Tests:

Relative Humidity as recorded on Honeywell Recorder.

_____ (45 %) _____ (40 %)
Max. Min.

Initials Date

Relative Humidity Test in Room:

_____ (45 %) _____ (40 %)
Max. Min.

Initials Date

Position Reading

Air Pressure History:

Air Pressure at 0800 _____ (0.30 to 0.325)
1200 _____ (0.30 to 0.325)
1600 _____ (0.30 to 0.325)

Remarks: _____

MONTHLY MONITORING

DATA SHEET - STERILE TRANSFER ROOM #141

Particle Count

Counter Calibrated

Initials

Date

Data Obtained

Location

Total Count

Attach Digital Readout Data obtained from Particulate Counter to this Data Sheet.

Monthly Monitoring Completed

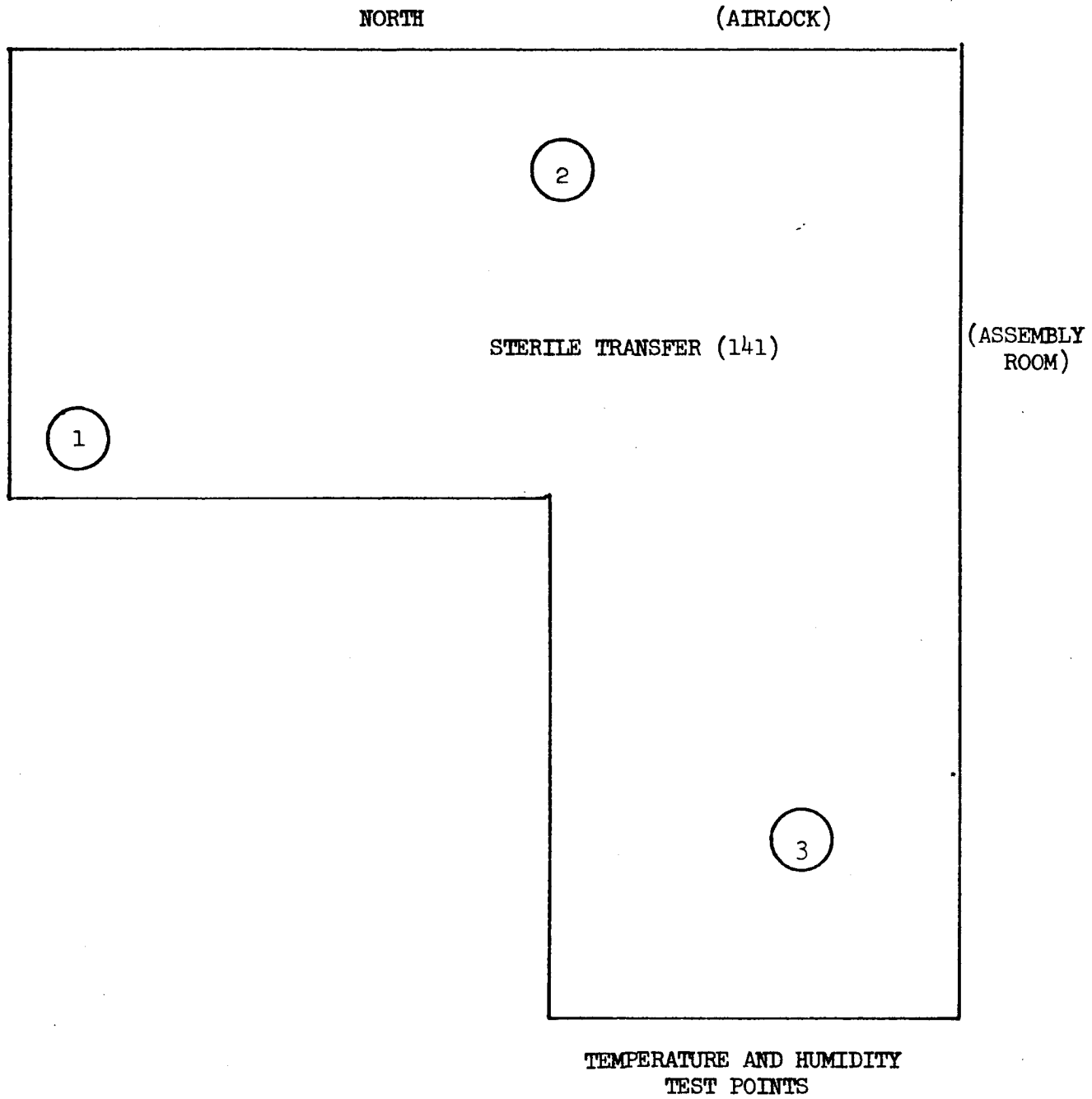
Accepted
Quality Control

Date

Remarks:

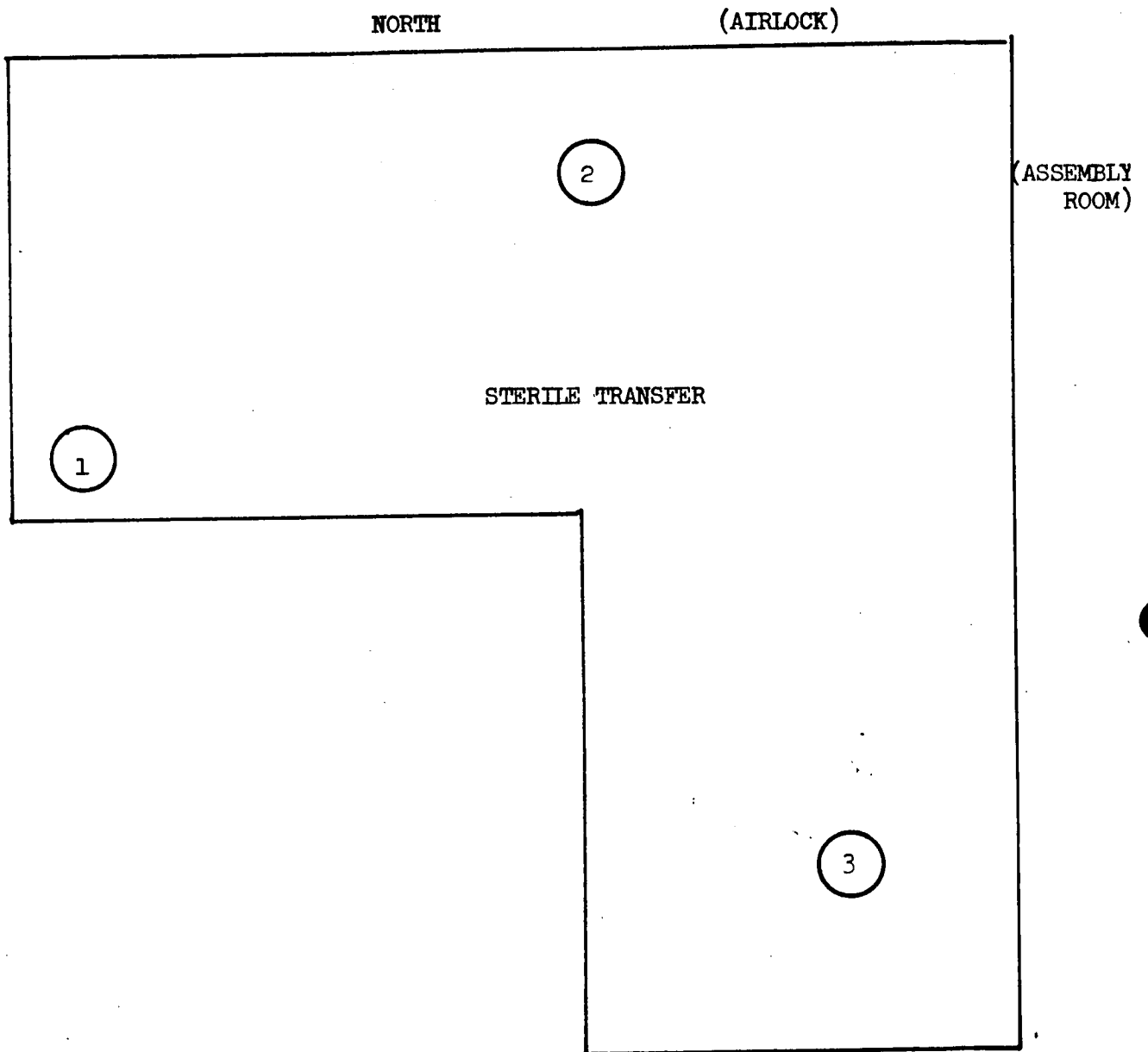
MONTHLY MONITORING

DATA SHEET - STERILE TRANSFER #141



MONTHLY MONITORING

DATA SHEET - STERILE TRANSFER #141



PARTICULATE COUNT
TEST POINTS.

MONITORING OF "HEPA" FILTERS

DATA SHEET - DRESSING ROOM SADL #138

Location	Reading	Free of Leaks	Leak Detected
A1			
A2			
A3			
A4			
A5			
B1			
B2			
B3			
B4			
B5			
C1			
C2			
C3			
C4			
C5			
D1			
D2			
D3			
D4			
D5			

Filter bank free of any leaks and
accepted.

Quality Assurance

Date

Remarks: _____

MONITORING OF "HEPA" FILTERS
DATA SHEET - DRESSING ROOM #138

	D	C	B	A

MONITORING OF "HEPA" FILTERS

DATA SHEET - ASSEMBLY ROOM #140

Location	Reading	Free of Leaks	Leak Detected	Location	Reading	Free of Leaks	Leak Detected
A1				C5			
A2				C6			
A3				C7			
A4				C8			
A5				C9			
A6				C10			
A7				D1			
A8				D2			
A9				D3			
A10				D4			
B1				D5			
B2				D6			
B3				D7			
B4				D8			
B5				D9			
B6				D10			
B7				E1			
B8	Crane	Crane	Crane	E2			
B9				E3			
B10				E4	Crane	Crane	Crane
C1				E5			
C2				E6			
C3				E7			
C4				E8			

MONITORING OF "HEPA" FILTERS
DATA SHEET - ASSEMBLY ROOM #140

Location	Reading	Free of Leaks	Leak Detected	Location	Reading	Free of Leaks	Leak Detected
E9				H4			
E10				H5			
F1				H6			
F2				H7			
F3				H8			
F4				H9			
F5				H10			
F6				<p>Filter bank free of any leaks and accepted. <u>Quality Assurance</u></p> <p style="text-align: right;">_____ Date</p> <p>Remarks: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>			
F7							
F8							
F9							
F10							
G1							
G2							
G3							
G4							
G5							
G6							
G7							
G8							
G9							
G10							
H1							
H2							
H3							

2

B-59

MONITORING OF "HEPA" FILTERS

DATA SHEET - DRESSING ROOM EASL #118

Location	Reading	Free of Leaks	Leak Detected
A1			
A2			
A3			
A4			
A5			
A6			
B1			
B2			
B3			
B4			
B5			
B6			
C1			
C2			
C3			
C4			
C5			
C6			
D1			
D2			
D3			
D4			
D5			
D6			

Filter bank free of any leaks and
accepted.

Quality Assurance

Date

Remarks: _____

MONITORING OF "HEPA" FILTERS
DATA SHEET - DRESSING ROOM #118

				1
				2
				3
				TOP
				4
				5
				6

MONITORING OF "HEPA FILTERS

DATA SHEET - BIO-ASSEMBLY ROOM #118

Location	Reading	Free of Leaks	Leak Detected	Location	Reading	Free of Leaks	Leak Detected
A1				C2			
A2				C3			
A3				C4			
A4				C5			
A5				C6			
A6				C7			
A7				C8			
A8				C9			
A9				C10			
A10				C11			
A11				C12			
A12				D1			
B1				D2			
B2				D3			
B3				D4			
B4				D5			
B5				D6			
B6				D7			
B7				D8			
B8				D9			
B9				D10			
B10				D11			
B11				D12			
B12				E1			
C1				E2			

MONITORING OF "HEPA" FILTERS

DATA SHEET - BIO-ASSEMBLY ROOM #118

Location	Reading	Free of Leaks	Leak Detected	Location	Reading	Free of Leaks	Leak Detected
E3				G4			
E4				G5			
E5				G6			
E6				G7			
E7				G8			
E8				G9			
E9				G10			
E10				G11			
E11				G12			
E12				H1			
F1				H2			
F2				H3			
F3				H4			
F4				H5			
F5				H6			
F6				H7			
F7				H8			
F8				H9			
F9				H10			
F10				H11			
F11				H12			
F12				Filter bank free of any leaks and			
G1				accepted.			
G2				<div style="text-align: right;"> <u>Quality Assurance</u> </div>			
G3				<div style="text-align: right;"> <u>Date</u> </div>			

MONITORING OF "HEPA" FILTERS
DATA SHEET - BIO-ASSEMBLY ROOM #118

	A	B	C	D	E	F	G	H
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								